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1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF NEW YORK

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3 UNITED STATES OF AMERICA,

4 v.

20 Cr. 160 (MKV)

5 SETH FISHMAN,

6 Defendant.

Trial

7 -----x

New York, N.Y.  
January 25, 2022  
9:40 a.m.

9 Before:

10 HON. MARY KAY VYSKOCIL,

11 District Judge  
12 -and a Jury-

13 APPEARANCES

14 DAMIAN WILLIAMS

United States Attorney for the  
Southern District of New York

15 BY: ANDREW C. ADAMS

SARAH MORTAZAVI

16 ANDEN F. CHOW

Assistant United States Attorneys

17 SERCARZ & RIOPELLE, LLP

Attorneys for Defendant Fishman

18 BY: MAURICE H. SERCARZ

19 -and-

LAW OFFICE OF MARC FERNICH

20 BY: MARC A. FERNICH

21 ALSO PRESENT: KARLINE JUNG, Paralegal Specialist

M1PTFIS1

(Case called, jury not present)

DEPUTY CLERK: Counsel, starting with the government, please state your name for the record.

MS. MORTAZAVI: Good morning, Sarah Mortazavi, Andrew Adams and Anden Chow and for the government.

MR. SERCARZ: For the defendant Seth Fishman, Maurice Sercarz and Marc Fernich. The defendant is present in court.

THE COURT: Good morning, counsel, and good morning, Dr. Fishman. Good morning to Mr. McDaniel, our court reporter.

Before we go any further, I just want to make clear on the record exactly where we're at.

As you all know, yesterday counsel for Mr. Giannelli tested positive for Covid, having been tested pursuant to the new protocols that were put in place. I announced to everyone, pursuant to Federal Rule of Criminal Procedure 26.3, that it was my intent, based on that test, to declare a mistrial, but gave people the opportunity to be heard.

Mr. Fasulo moved for a mistrial with respect to Ms. Giannelli. The government moved to sever, and then Mr. Fasulo moved for the mistrial with respect to Ms. Giannelli. I granted the motion for a mistrial with respect to Ms. Giannelli, and obviously that's a granting of the motion to sever then.

Dr. Fishman's counsel then argued that they thought that a mistrial was in order then with respect to Dr. Fishman

M1PTFIS1

1 as well. I gave both counsel an opportunity to submit written  
2 submissions at the end of the day. I instead received from the  
3 government a submission over lunchtime. When we resumed in the  
4 afternoon, Dr. Fishman's counsel argued on the record. I  
5 invited and gave you ample opportunity to make a written  
6 submission by the end of the day yesterday and to propose a  
7 limiting instruction that would be given to the jury if I did  
8 not declare a mistrial. I received nothing further in writing  
9 from either party.

10 So I note that defense counsel, in its oral argument  
11 yesterday, agreed with the government's recitation of all of  
12 the governing legal standards which are laid out in the  
13 government's letter at Docket Entry 702. Specifically, both  
14 sides now agree that the standard for retroactive misjoinder,  
15 which is what counsel for Dr. Fishman seemed to be arguing in  
16 support of its motion for a mistrial, is compelling prejudice.  
17 And the relevant guidance from the Second Circuit is set forth  
18 in *United States v. Hamilton*, 334 F.3d 170, 181 (2d Cir. 2003),  
19 and *United States v. Jones*, 16 F.3d 487, 493 (2d Cir. 1994).  
20 Dr. Fishman's counsel also acknowledged that the Court has  
21 discretion with respect to these issues, citing *United States*  
22 *v. Cardascia*, 951 F.2d 474, 482, (2d Cir. 1991).

23 The Court does not find that Dr. Fishman has suffered  
24 or would suffer any compelling prejudice from the mistrial with  
25 respect to Ms. Giannelli or from the defense strategy that

M1PTFIS1

1 Ms. Giannelli's counsel pursued at the beginning of the trial,  
2 her subsequent mistrial, or the combination of the two factors.  
3 And I will note for the record that Dr. Fishman's counsel was  
4 emphatic that but for the development with respect to  
5 Mr. Fasulo and Covid, it had not yet come to a landing on  
6 whether it intended to make any kind of a motion, and that  
7 yesterday's developments were the precipitating factor in its  
8 seeking a mistrial.

9 With respect to Ms. Giannelli's absence for the rest  
10 of the trial, as I noted yesterday, it's not infrequent that a  
11 defendant might plead guilty in the middle of a trial. A  
12 defendant might decide in the middle of trial to testify  
13 against a remaining defendant. The case law makes clear that  
14 even in those circumstances there would not be grounds for a  
15 mistrial so long as the trial judge gives appropriate  
16 cautionary instructions to the jury. And I would cite  
17 specifically to *United States v. Barret*, 848 F.3d 524, 534 (2d  
18 Cir. 2017).

19 It seems to the Court that all of the arguments that  
20 Ms. Giannelli's counsel made were completely foreseeable when  
21 Dr. Fishman's counsel and Dr. Fishman consented to be tried  
22 with her, and her absence from the rest of this trial does not  
23 foreclose any line of defense that Dr. Fishman is entitled to  
24 pursue. In fact, in of the Court's view, it might make it  
25 easier for him to pursue certain lines of defense. It is not

M1PTFIS1

1 infrequent that co-defendants seek to place blame on one  
2 another, and that circumstance does not require severance.  
3 See, *United States v. Villegas*, 899 F.2d, 1324, 1346 (2d Cir.  
4 1990).

5 Mr. Fernich, when he was arguing to me, stressed that  
6 it had been his intent to cross-examine Ms. Giannelli, which  
7 obviously he can no longer do, based on his understanding that  
8 Mr. Fasulo made a representation in his opening statement that  
9 Ms. Giannelli intended to testify. Even if that is accurate,  
10 there was absolutely no guarantee that Ms. Giannelli would  
11 testify and she was never under any obligation to do so. And  
12 in fact, I so instructed the jury in my preliminary  
13 instructions.

14 As Mr. Fernich acknowledged, trials are fluid. I  
15 appreciate that he and Mr. Sercarz may have formulated a  
16 particular strategy that they were planning to pursue in light  
17 of Ms. Giannelli's defense during the first day and a half of  
18 trial. Counsel will need to adapt. That's what it means to  
19 say a trial is a fluid situation.

20 Dr. Fishman has received and will continue to receive  
21 a fair trial. Contrary to what counsel argues, a cautionary  
22 instruction is adequate to protect Dr. Fishman's constitutional  
23 rights. So the motion by Dr. Fishman for a mistrial is denied  
24 and we will move forward with the trial today.

25 Now I have copies for counsel of the instruction that

M1PTFIS1

1 I intend to give the jury.

2 Ms. Dempsey, if you could hand this out, I would  
3 appreciate it.

4 I did receive a proposed instruction from the  
5 government yesterday at the lunch break. As I think I said on  
6 the record yesterday, I had some reactions to it and proposed  
7 modifications. I am giving you the proposed instruction I  
8 would intend to give, and I will give everyone a few moments to  
9 look it over and give me any comments.

10 MR. ADAMS: Thank you, your Honor. It looks good to  
11 the government.

12 THE COURT: Thank you.

13 MR. FERNICH: Obviously, without prejudice to the  
14 prior arguments, the limiting instruction is appropriate.

15 THE COURT: Thank you very much.

16 All right. Ms. Dempsey, were our jurors all  
17 assembled?

18 DEPUTY CLERK: Not yet.

19 THE COURT: So we'll stand in recess until roughly  
20 10 o'clock. Ms. Dempsey will let me know when our jurors are  
21 all here and we will pick up.

22 Is your witness ready? You were in the middle of a  
23 witness.

24 MS. MORTAZAVI: Yes, your Honor, we do have our  
25 witness ready. And we have one matter to bring to the Court's

M1PTFIS1

1 attention.

2 THE COURT: Sure.

3 MS. MORTAZAVI: We have transcript binders I believe  
4 we brought to the Court's attention before. Defense counsel  
5 has reviewed them. And they're binders containing  
6 transcriptions of various wire recordings that we would like to  
7 make available to the jurors. So if it's amenable to the  
8 Court, we could either place them in the jurors' seats now or  
9 do it after the jurors have assembled.

10 THE COURT: You mean for them to follow along?

11 MS. MORTAZAVI: That's right, your Honor.

12 THE COURT: Okay. Why don't you put them on their  
13 seats while we are in recess so that that way when they arrive,  
14 we don't have to hold things up.

15 MS. MORTAZAVI: Certainly. Thank you, your Honor.

16 THE COURT: Okay. Anything from you, Mr. Fernich or  
17 Mr. Sercarz?

18 MR. FERNICH: Judge, I don't mean to be a pest.  
19 Turning back to the limiting instruction for a minute, the  
20 instruction anticipated what had been my paramount concern. A  
21 subsidiary concern, I would like to add something in there that  
22 the jury is to disregard all arguments and evidence and  
23 questioning and answers elicited by Giannelli and her counsel.

24 MS. MORTAZAVI: Your Honor, we would object to such an  
25 instruction. Obviously the evidence that was elicited against

M1PTFIS1

1 Ms. Giannelli is relevant to Dr. Fishman, as they're  
2 co-conspirators.

3 THE COURT: I'm not going to instruct anything with  
4 respect to evidence, and I have already instructed that opening  
5 statements are not evidence. I will, to the extent it's not  
6 included in what you all proposed in the joint instructions for  
7 the end of the trial, obviously I will include that then. And  
8 if you want me specifically to mention Mr. Fasulo's opening,  
9 you can propose that, but right now I'm not going to amend this  
10 proposed instruction.

11 MR. FERNICH: I'm less concerned, actually, about the  
12 opening statement. I understand what is going to -- you have  
13 already given an instruction about that, it will be reiterated.

14 I will join issue with Ms. Mortazavi on the  
15 admissibility of the prior evidence that an absent order --

16 THE COURT: I'm sorry, I'm not hearing you fully.  
17 Could you sit and talk into the microphone?

18 MR. FERNICH: Sorry, Judge. I'm not so concerned  
19 about the opening statement, for the reasons your Honor  
20 articulated. Your Honor has given an instruction and will give  
21 another instruction in the ordinary course.

22 I will join issue, though, with Ms. Mortazavi on the  
23 admissibility of the testimony that an absent defendant has now  
24 elicited. We can't react to that. Insinuations were left by  
25 the defense lawyer. I don't think that belongs in the record

M1PTFIS1

1 anymore. If the government wants to elicit its own proof as to  
2 what Ms. Giannelli did or did not do as a putative  
3 co-conspirator in the case, that's on them, but that party is  
4 no longer involved in this case, and that evidence, in my view,  
5 all that happened under the baton of Mr. Fasulo and  
6 Ms. Giannelli should now be stricken from the record. We're  
7 involved in a separate trial now and who knows how Mr. Fasulo  
8 would have amended that or supplemented that or footnoted that  
9 going forward, and we shouldn't have to contend with that  
10 evidence moving forward.

11 THE COURT: I do hear your argument and I do  
12 understand the concern. I need input from the parties on this,  
13 to be perfectly honest.

14 MR. FERNICH: Okay. It's a bit of a novel issue.

15 MS. MORTAZAVI: Your Honor, let me say this: The  
16 point of adapting to changed circumstances is not having a  
17 second bite at the apple and pretending what the jury has heard  
18 has not actually occurred. The point is to adapt moving  
19 forward. And I don't think that we need to strike any  
20 responses by certain of the witnesses to a line of questions as  
21 if it was somehow inappropriately placed before the jury or  
22 somehow prejudicial to Dr. Fishman. The point is not to erase  
23 what has happened, the point is to instruct the jury how  
24 they're going to weigh the evidence moving forward.

25 THE COURT: So let me say this: I am telling you, in

M1PTFIS1

1 all candor, I honestly do not know the answer here, which is  
2 why I told you I want input from the parties.

3 My gut tells me the following: If Ms. Giannelli had  
4 taken the stand and offered evidence and then we have a  
5 mistrial and she disappears, I think that would probably have  
6 to be stricken. But the fact that Mr. Fasulo, on her behalf --  
7 as did you or Mr. Sercarz on behalf of your client --  
8 cross-examined witnesses, does not strike me as something that  
9 would have to be stricken.

10 But I honestly do not know the answer to this, and I'm  
11 going to give you a short time to try to give me something to  
12 lean on. Otherwise, as I say, my sense is that that  
13 instruction is not appropriate. The opening, yes, but I have  
14 already given that and I will give it again at the end.

15 MR. FERNICH: I don't know the answer. I'm being  
16 candid with you. It seems to me, though, it's not limited to  
17 our opportunity to -- or lack thereafter -- to cross-examine  
18 Giannelli, who may or may not have appeared and testified. But  
19 we have a strategic call to make about whether to cross-examine  
20 subsequent witnesses about the assertions made by Adams in  
21 response to questioning and evidence elicited by Mr. Fasulo.

22 THE COURT: Right. You have to make that decision.

23 It seems to me evidence is evidence. And suppose she  
24 had pled guilty and was out of the case. In the cases that we  
25 looked at last night to try to formulate my ruling, never did

M1PTFIS1

1 we see a limiting instruction after a defendant disappeared  
2 from a case because of a plea that any of the evidence that had  
3 been adduced up to that point needed to be stricken, and that's  
4 what is guiding my thinking here.

5 MR. FERNICH: That's a fair point. I will take a  
6 look, and I take that point.

7 THE COURT: All right.

8 MS. MORTAZAVI: Your Honor, if I may add something to  
9 this argument, which is it's not as simple as Mr. Fernich is  
10 making it sound.

11 THE COURT: I don't know if he's making it sound  
12 simple, he's being honest that he doesn't know.

13 MS. MORTAZAVI: It's not merely the fact of removing  
14 the questions and answers by Mr. Fasulo because counsel for  
15 Dr. Fishman had the opportunity for recross and government had  
16 the opportunity for redirect.

17 THE COURT: Yes, I said that.

18 MS. MORTAZAVI: Certainly. I apologize if I missed  
19 it, your Honor.

20 THE COURT: I didn't say it in those exact words, I  
21 said there was opportunity for them to conduct whatever  
22 examinations they wanted.

23 MS. MORTAZAVI: And I think it's more complex to try  
24 to do the surgical correction that Mr. Fernich is proposing  
25 than to simply leave the evidence as it is.

M1PTFIS1

1 THE COURT: That is my instinct.

2 MR. FERNICH: That part is not complex, you just  
3 strike out the entire examination.

4 THE COURT: No, I don't think it's that simple,  
5 Mr. Fernich, because that might have impacted what the  
6 government might have done or might have impacted what you  
7 might have done. To go back retroactively and try to alter the  
8 record, it seems to me, creates more problems in terms of the  
9 fairness of the trial. So that's my instinct.

10 Why don't we take a break. If you want to find  
11 contrary authority to bring to my attention, I will consider  
12 it, but otherwise my ruling is I am not going to include  
13 anything in the instruction about striking anything from the  
14 record.

15 MR. FERNICH: I will take a look. And just to be  
16 clear, I won't belabor it, we understand each other. My  
17 concern is sort of different from -- we understand we had the  
18 opportunity to cross and recross Ms. Adams, but it's certainly  
19 not unheard of in a trial to get one prosecution witness to  
20 impeach the testimony of another, either implicitly or  
21 explicitly, and that's a common weapon in our arsenal. Now  
22 we're in the horns of a dilemma: Do we do that or not? And  
23 it's tough, and it depends on whether that evidence still  
24 exists or not.

25 THE COURT: The evidence still exists.

M1PTFIS1

1 We'll stand in recess. Ms. Dempsey will check on the  
2 availability of our jurors. If you find something that you  
3 want to call to my attention, I am open to hearing it, but  
4 that's my ruling.

5 We'll stand in recess. Thank you.

6 MS. MORTAZAVI: Thank you, your Honor.

7 (Recess taken)

8 THE COURT: I'm told our jurors have all arrived, so  
9 we're ready to resume.

10 Anything further from you, Mr. Sercarz or Mr. Fernich?

11 MR. FERNICH: Yes, your Honor, just briefly. I  
12 understand your Honor's preliminary ruling on the instruction  
13 point. I will add to the record the following: Because the  
14 government has not shown that testimony elicited by Giannelli  
15 would have been admissible against Fishman had their trials  
16 initially been severed, I'm maintaining my position that the  
17 testimony should be stricken and disregarded. And for the  
18 present I will cite for that *U.S. v. Flores*, 362 F.3d 1030,  
19 1041 (8th Cir. 2004).

20 THE COURT: Anything from our circuit?

21 MR. FERNICH: Eighth Circuit.

22 THE COURT: I said do you have anything from our  
23 circuit?

24 MR. FERNICH: No, but the Eighth Circuit case cites to  
25 two other cases, and they're all interpreting language in

M1PTFIS1

1     *Zafiro*, which says -- we talked about *Zafiro* yesterday. *Zafiro*  
2     says that in the ordinary course testimony by a severed  
3     co-defendant would not ordinarily be stricken if it would have  
4     been inadmissible -- if it would have been admissible in a  
5     separate trial. That's what I was able to find in the moment.

6             THE COURT: All right. First of all, it's not in the  
7     moment. I gave you yesterday evening to submit whatever you  
8     wanted to submit and you chose to submit nothing, including  
9     nothing on a limiting instruction. So the record needs to be  
10    clear about that point.

11            I will take a quick look at the case, but anything  
12    from you, Mr. Adams?

13            MR. ADAMS: Only that, number one, there's not been a  
14    single objection by Mr. Fishman to any question that Mr. Fasulo  
15    asked throughout the course of examination. That's because  
16    everything he asked of those witnesses was admissible in this  
17    case. It would have been admissible in a separate case against  
18    Fishman. All statements by Ms. Giannelli that have been  
19    elicited so far have been in furtherance of Fishman's  
20    conspiracy and would be admissible even in separate trials.  
21    But the core fact is if they would have been admissible to  
22    Mr. Fishman, he had the opportunity to object at the time and  
23    did not.

24            (Continued on next page)

M1PPFIS2

1 MR. FERNICH: I have the testimony calling  
2 Dr. Fishman -- eliciting evidence from Courtney Adams to  
3 support the notion that -- and I think the word "sheep master"  
4 was even used in the examination. Obviously, we didn't object  
5 at the time because the calculation was different, because we  
6 were having joint trial, and we'd have the opportunity, as the  
7 trial went on, to rebut that.

8 Standing on its own, that certainly, certainly would  
9 not have been admissible against Dr. Fishman in a separate  
10 trial. That argument strains credulity.

11 THE COURT: You have the same opportunity to rebut now  
12 that you had before, and as I said earlier, to the extent  
13 you're claiming you would have rebutted it by cross-examining  
14 Ms. Giannelli, it was not a foregone conclusion that she was  
15 going to testify. She had the right to change her mind at any  
16 moment.

17 So the Court holds the same view as I ruled. I'm not  
18 going to add anything to the limiting instruction about  
19 questioning by Mr. Fasulo, and I am not going to strike any  
20 evidence.

21 MR. FERNICH: I understand. I'm not -- I appreciate  
22 your Honor's ruling. For the record, I do want to say one more  
23 thing. Even if Ms. Giannelli had rescinded the -- I've never  
24 heard a representation like that by a lawyer in an opening,  
25 that you will hear from Ms. Giannelli.

M1PPFIS2

1           Even that, had that been rescinded, though, we would  
2           have had the opportunity to seek to call Ms. Giannelli on our  
3           own case, and that opportunity is gone by virtue of her certain  
4           invocation of the Fifth Amendment at this point, given that  
5           we've been severed. So I'll just add that to the record. I  
6           don't want to belabor it. I just want to make sure my record  
7           is clear.

8           THE COURT: You would not have had the opportunity to  
9           call her. As a co-defendant, she is entitled not to take the  
10          stand and to say nothing, and you would not be free to comment  
11          on that.

12          MR. FERNICH: If she invoked, I agree with you.

13          THE COURT: All right. The other thing, I do not find  
14          the case that you've cited to me as persuasive on this point.  
15          I mean, just for the record -- and then we're going to move on  
16          because the jurors are waiting outside -- that case says "a  
17          fair trial does not include the right to exclude relevant and  
18          competent evidence.

19          A defendant normally would not be entitled to exclude  
20          the testimony of a former co-defendant if the District Court  
21          did sever their trials, and we see no reason why relevant  
22          competent testimony would be prejudicial merely because the  
23          witness is also a co-defendant."

24          So you have my ruling. I'm going to ask my clerk to  
25          let Ms. Dempsey know we're ready for the jury to come in, and I

M1PPFIS2

1 will give the limiting instruction that you have, both sides,  
2 seen and have no objection to. Correct, Mr. Adams?

3 MR. ADAMS: Correct, your Honor.

4 THE COURT: Mr. Fernich?

5 MR. FERNICH: Not other than the objection previously  
6 launched.

7 THE COURT: The objection is that you want me to  
8 strike evidence, but the text of what I gave you, you have no  
9 objection to, you just want more added?

10 MR. FERNICH: That is correct.

11 THE COURT: Okay. Thank you.

12 MR. ADAMS: And, your Honor, shall I call Agent  
13 Folensbee to the stand, get him up there while --

14 THE COURT: No, I think you should wait for the jury.  
15 I think he should come in when the jury is sitting.

16 MR. ADAMS: Okay.

17 THE COURT: And I'm sorry, what was his name again?

18 MR. ADAMS: Folensbee.

19 THE COURT: I'm sorry?

20 MS. MORTAZAVI: His name is Folensbee, your Honor,  
21 F-o-l-e-n-s-b-e-e.

22 THE COURT: All right, thank you. And Agent or  
23 Mister?

24 MS. MORTAZAVI: Mister. He was the staff operations  
25 specialist.

M1PPFIS2

1 THE COURT: Thank you.

2 (Pause)

3 (Jury present)

4 All right. Please be seated, everyone.

5 Good morning, ladies and gentlemen. Let me first say  
6 thank you very, very much for your patience yesterday. I'm  
7 sorry for the disruption and the imposition on you. I  
8 appreciate your patience again this morning.

9 The lawyers and I had some legal issues that we had to  
10 sort through and talk about outside of your presence, and that  
11 was the reason why we first had you standing by yesterday and  
12 then ultimately realized that we weren't going to get to any  
13 testimony, and so it was fine for you to leave for the day  
14 yesterday. So I appreciate your patience.

15 From time to time there are legal issues that come up  
16 that I do need to talk to the lawyers about outside your  
17 presence, but we'll try to keep that to a minimum, do it over  
18 lunch break or the morning or afternoon break so we don't  
19 impose on all of you, but thank you again.

20 So before we resume the testimony, I have further  
21 instructions that I want to give to all of you. Ms. Giannelli  
22 is no longer on trial. You are not being asked to render a  
23 verdict as to her. Now, you are not to be concerned with  
24 Ms. Giannelli, nor should you speculate about the reasons why  
25 she is no longer a part of this trial. The trial against

M1PPFIS2

1 Dr. Fishman will be going forward.

2 This development may not effect or influence your  
3 verdict with respect to Dr. Fishman in any way. You must base  
4 your verdict as to Dr. Fishman solely on the basis of the  
5 evidence, or lack of evidence, against him. Ms. Giannelli's  
6 absence is not evidence of either defendant's guilt, and you  
7 may not draw any negative inference against Dr. Fishman based  
8 on the fact that Ms. Giannelli's trial is not proceeding at  
9 this time.

10 All right? So, Mr. Adams, would you please re-call  
11 Mr. Folensbee, who was the witness we were hearing from when we  
12 broke on Friday, I believe.

13 MR. ADAMS: Certainly, your Honor.

14 THE COURT: Oh, and ladies and gentlemen, you also  
15 have on your chair a binder that counsel left for you because  
16 they will be using some of what's in those binders during the  
17 examination this morning because we thought it was just easier  
18 and more efficient to have it there for you, but they'll let  
19 you know when you need it.

20 Good morning, sir. Thank you for being here, and I  
21 remind you that you remain under oath, sir. Thank you.

22 Ms. Mortazavi.

23 MS. MORTAZAVI: Thank you, your Honor.

24 DANIEL FOLENSBEE,  
25 DIRECT EXAMINATION (Resumed)

M1PPFIS2

Folensbee - Direct

1 BY MS. MORTAZAVI:

2 Q. Good morning, Mr. Folensbee.

3 A. Good morning.

4 Q. Just to remind the jury, because you had begun your  
5 testimony on Friday, and we're resuming today. You are a staff  
6 operations specialist with the FBI; is that right?

7 A. Yes.

8 Q. And when you last testified Friday afternoon, you discussed  
9 your participation in a search that took place between  
10 October 27th and 28th, 2019; is that correct?

11 A. Yes.

12 Q. And the address of the search was 3500 Northwest 2nd  
13 Avenue, Unit 723, Boca Raton, Florida; is that also right?

14 A. Yes, that is correct.

15 Q. And again, to remind the jurors, you were the photographer  
16 for that particular search; is that correct?

17 A. That is correct.

18 Q. Ms. Jung, could you please pull up Government Exhibits  
19 4000, 4031 and 4032, and these are all in evidence. If you  
20 could please publish it for the jury as well.

21 Mr. Folensbee, could you just remind us again about  
22 the interior of the premises that was searched with reference  
23 to these exhibits?

24 A. Yes. The left photo is the entrance to the office area,  
25 and the door in the back in the photo leads to the storage

M1PPFIS2

Folensbee - Direct

1 area, which is on the right two photos.

2 Q. And on Friday, you previously discussed the photo to the  
3 right side of the screen at the bottom, I believe that's  
4 Government Exhibit 4032, correct?

5 A. Yes.

6 Q. And you testified about the rubber bins that were stacked  
7 on the shelves in that unit, correct?

8 A. Yes.

9 Q. Do you recall what was inside those rubber bins, generally  
10 speaking?

11 A. Vials of drugs.

12 Q. Ms. Jung, could you pull up Government Exhibit 4001 and  
13 4002.

14 Mr. Folensbee, are these refrigerators that were found  
15 within the premises?

16 A. Yes, they are.

17 Q. And do you see on the left side of the screen that's  
18 Government Exhibit 4001, that there appears to be a white board  
19 that's attached to one of the fridges?

20 A. That's correct.

21 Q. All right. And looking to Government Exhibit 4002, could  
22 you please read the names that are listed on that white board?

23 A. We have AC, ACTH, ATM, ATQ Red, BPR, one that I can't read,  
24 Cobalt Chloride, another one that can't read, EquiAce, EquiCam,  
25 Equitosan, FAB, FAB plus, HCG 11,000, NPPI-34D, P3, Serum,

M1PPFIS2

Folensbee - Direct

1 SODHSP 125, SODHSP-C, and Wake Me Up.

2 Q. And, Ms. Jung, could you please pull up Government  
3 Exhibit 4003 and 4005.

4 Mr. Folensbee, what are we looking at here?

5 A. We are looking at one of the refrigerators found at the  
6 search location and one of the drawers inside that  
7 refrigerator.

8 Q. And is that in reference -- and you mentioned one of the  
9 drawers, is that Government Exhibit 4005?

10 A. Yes, ma'am.

11 Q. Do you see that there's a tape with some writing on it on  
12 that shelf?

13 A. Yes.

14 Q. Could you please read that out loud, to the extent you can  
15 understand it?

16 A. ITP, 20 milliliter amber, DOM 7.19.

17 Q. And, Ms. Jung, could you please pull up Government  
18 Exhibits 4036, 4037 and 4047.

19 And, again, Mr. Folensbee, are we looking at the  
20 interior of fridges that were found on the premises?

21 A. Yes, we are.

22 Q. Looking at Government Exhibit 4036 for the moment, do you  
23 see that there are rubber containers contained within the  
24 fridge with tape on them that appears to contain some writing?

25 A. Yes, I do.

M1PPFIS2

Folensbee - Direct

1 Q. Could you please read out what's written on those pieces of  
2 tape?

3 And, Ms. Jung, if we could expand that particular  
4 Exhibit 4036 so that it's legible?

5 A. One says NPX1, a couple letters I can't read, 10  
6 milliliters, DOM 6.18.

7 THE COURT: Excuse me. Are we able to make that  
8 bigger? Can you make that bigger?

9 MS. MORTAZAVI: We'll try. Ms. Jung, could you focus  
10 on the top shelf, make that bigger?

11 THE COURT: Thank you very much.

12 A. Okay. So the one on the left, NPX1, old, in quotation  
13 marks, 10 milliliter, DOM 6.18.

14 Q. And on the other container full of bottles?

15 A. AICAR, Equi-Ace, DOM 8.19.

16 Q. Thank you.

17 Ms. Jung, could we please focus on Government  
18 Exhibit 4037.

19 Looking again at the top shelf, could you please read  
20 those labels, Mr. Folensbee, starting with the top left and  
21 then moving down and to the right side of the screen?

22 A. The top left, a couple letters and Equine New 7.16; bottom  
23 left Glutathione; bottom right, Equitriopian; top right, ATQB0.

24 Q. Thank you.

25 Ms. Jung, could you please pull up Government

M1PPFIS2

Folensbee - Direct

1 Exhibit 4019 and 4020.

2 Mr. Folensbee, are you able to see the labels that are  
3 on this cardboard container?

4 A. Yes.

5 Q. And looking to Government Exhibit 4047 -- I'm sorry 4020,  
6 my mistake, which is on the right side of your screen, could  
7 you please read out the address of what appears to be the  
8 sender on this shipping label?

9 A. 6 Teda Building, 87 Wing Lok Street, Sheung Wan, Hong Kong  
10 Island, 999077, Hong Kong.

11 Q. And is there a business name associated with that?

12 A. Yes, Ancheng Pharma Limited.

13 Q. Thank you. And there appears to be a line with product  
14 written on it. Would you please read out the name of the  
15 product that appears?

16 A. Diclazuril.

17 Q. Okay. And, sir, do you see a sticker on this container  
18 that appears to contain a company name or a branded sticker?

19 A. Yes, Equi-Science on the top, top right.

20 Q. All right. Ms. Jung, could you please pull up Government  
21 Exhibit 4022 and 4023.

22 Mr. Folensbee, we reviewed some of these exhibits  
23 previously when you testified before. I just want to ask you,  
24 looking at these two exhibits, do you see any of these labels  
25 that contain the name Equestology on them?

M1PPFIS2

Folensbee - Direct

1 A. No, ma'am.

2 Q. Do you see any of these labels that appear to contain the  
3 address that was searched, 3500 Northwest Second Avenue?

4 A. No.

5 Q. Ms. Jung, could you please pull up Government Exhibit 4024  
6 and 4027.

7 Mr. Folensbee, were these also labels that were found  
8 at the address that was searched?

9 A. Yes.

10 Q. And looking at these rolls of labels, again, could you  
11 please tell us if any of these contain the company name  
12 Equestology?

13 A. No.

14 Q. Do any of these contain the address that was searched?

15 A. No.

16 Q. Ms. Jung, could you please pull up Government Exhibit 4028  
17 and 4029.

18 Mr. Folensbee, is this one of the -- well, on the  
19 right side, one of the bottles that was found, and on the left  
20 side, collection of the same type of bottles that was found on  
21 the premises of the search?

22 A. Yes.

23 Q. Could you, to the extent you can, read out the product name  
24 and information on the label that appears on this particular  
25 bottle with reference to Government Exhibit 4029?

M1PPFIS2

Folensbee - Direct

1 A. Yes. GNRH, Gonadorelin diacetate, 20 milliliter,  
2 multiple-dose vial.

3 Q. Thank you, sir.

4 Ms. Jung, could you please pull up Government  
5 Exhibit 4034 and 4035, and could you zoom in with respect to  
6 4035, Ms. Jung, on the single blue packaging that appears in  
7 that picture.

8 And, Mr. Folensbee, could you read the name of this  
9 product?

10 A. Equitosan.

11 Q. And the information that appears under it, starting with, I  
12 believe, it's 20 milliliter?

13 A. 250 milligrams/milliliter, 20 milliliter multi-dose vial,  
14 pentosan polysulfate.

15 Q. Thank you, sir.

16 Ms. Jung, could you please pull up Government  
17 Exhibit 4024, 4043 and 4044, and could you focus, please,  
18 Ms. Jung, on the top right exhibit.

19 And, Mr. Folensbee, could you read out the name on  
20 this label, what appears to be the name of this product?

21 A. Homeopathic analgesic.

22 Q. To the extent you can read it, or we can have Ms. Jung  
23 expand it, could you please read the directions for this  
24 particular product?

25 A. Administer 2 cc's intravenously only, four to six hours

M1PPFIS2

Folensbee - Direct

1 prior to strenuous exercise.

2 Q. And, Mr. Folensbee, looking at Government Exhibit 4043, is  
3 that a single bottle that is the same bottle that appears in  
4 Government Exhibit 4044?

5 A. Yes.

6 Q. That's the bottle with the pink cap, correct?

7 A. Yes.

8 Q. And also looking at Government Exhibit 4044, the tub that  
9 is beside it that contains a collection of bottles with pink  
10 caps, are those multiple bottles of the same type as the  
11 homeopathic analgesic that we were just discussing?

12 A. Yes, they are.

13 MS. MORTAZAVI: Your Honor, no further questions.

14 THE COURT: Thank you.

15 MR. SERCARZ: Can I have one moment?

16 THE COURT: Sure.

17 (Pause)

18 MR. SERCARZ: No questions, your Honor.

19 THE COURT: All right. Thank you.

20 All right. Thank you, sir. You're excused.

21 (Witness excused)

22 Mr. Adams, your next witness?

23 MR. ADAMS: Thank you, your Honor. The government  
24 calls Dr. Jean Bowman.

25 MS. MORTAZAVI: I'm sorry, your Honor. Before we call

M1PPFIS2

Folensbee - Direct

1 our next witness, we'd like to read into the record a  
2 stipulation.

3 THE COURT: All right. Do I have copies of the  
4 stipulation?

5 MR. SNIM: It should be in your binder, but Ms. Jung  
6 can pull up a copy. It is a government exhibit that's been  
7 marked as Government Exhibit 9011, and we'll also be reading in  
8 9014.

9 THE COURT: All right. If you're able to hand them  
10 up, that would be easier because I don't know which of these  
11 many binders we're working with and, frankly, if someone can  
12 provide the same binder that you gave the jurors to me.

13 MS. MORTAZAVI: I believe the Court does have a copy  
14 of the transcript binder.

15 THE COURT: Yes, but I can't find it.

16 MS. MORTAZAVI: We can amend that.

17 THE COURT: Thank you, Mr. Chow. I appreciate your  
18 help. Thank you.

19 All right. Put this on the screen. I can work with  
20 that. Thank you, Ms. Mortazavi. I'm sorry.

21 MS. MORTAZAVI: So reading into the record what's been  
22 marked as Government Exhibit 9011, which is the stipulation  
23 between the parties, given that it's the first stipulation of  
24 the day, I'll go ahead and read the introductory statements  
25 that we've read before.

M1PPFIS2

Folensbee - Direct

1           It is hereby stipulated and agreed, by and among the  
2           United States of America, by Damian Williams, United States  
3           Attorney for the Southern District of New York, Andrew C.  
4           Adams, Anden Chow and Sarah Mortazavi, Assistant United States  
5           Attorneys, of counsel, and Seth Fishman, defendant, by his  
6           attorney, Maurice Sercarz, Esquire, that:

7           In 2019, agents with the Federal Bureau of  
8           Investigation, FBI, conducted judicially authorized wiretap  
9           interception of wire and electronic communications over certain  
10          cellular phones.

11          The contents of each intercepted wire or electronic  
12          communication, the incoming and outgoing phone numbers  
13          associated with the communication, and when provided, the  
14          geo-location data including the coordinates of particular  
15          cellular telephone towers through which particular  
16          communications were routed by the relevant cellular services  
17          providers, e.g. T-Mobile, were recorded at the time each  
18          communication occurred.

19          Each recording and its associated data was then  
20          transferred to a computer system under the custody and control  
21          of the FBI. The government exhibits listed in schedules A, B,  
22          C and D to the stipulation are true and correct copies of  
23          portions of communications that were intercepted pursuant to  
24          such judicially authorized wiretaps in the manner described in  
25          paragraph 1 above.

M1PPFIS2

Folensbee - Direct

1 Schedule A lists calls and text messages intercepted  
2 over a cellular phone identified with the telephone number  
3 561-270-9286, subscribed to in the name of Seth Fishman. The  
4 9286 phone.

5 Schedule B lists calls and text messages intercepted  
6 over a cellular phone identified with the telephone number  
7 302-222-2220, subscribed in the name of Lisa Giannelli. The  
8 2220 phone.

9 Schedule C lists calls and text messages intercepted  
10 over a cellular phone identified with the telephone number  
11 954-557-7015, subscribed in the name of Jorge Navarro. The  
12 7015 phone.

13 Schedule D lists calls and text messages intercepted  
14 over a cellular phone identified with the telephone number  
15 570-991-3010, subscribed in the name of Susan M. Oakes. The  
16 3010 phone.

17 Government Exhibits 203, 204, 205 and 206, which are  
18 also listed in Schedule A to the stipulation, are true and  
19 correct copies of maps generated based on geo-location data  
20 provided by T-Mobile.

21 Government Exhibits 101-T through 199-T are true and  
22 accurate transcriptions and voice attributions of portions of  
23 intercepted wire communications described in paragraphs 1 and 2  
24 above, and are marked corresponding to the number assigned to  
25 the relevant recording.

M1PPFIS2

Folensbee - Direct

1 For example, Government Exhibit 101-AT is a transcript  
2 of the recording contained in Government Exhibit 101-A.

3 Also included as part of each transcript is true and  
4 accurate information regarding the time and/or date of the  
5 relevant recording and the participating phone numbers.

6 It is further stipulated and agreed, by and between  
7 the parties, that the aforementioned government exhibits and  
8 the stipulation, which is Government Exhibit 9011, may be  
9 received in evidence at trial.

10 Your Honor, the government offers Government Exhibits  
11 9011, 101-A through 115-C, 117-A through 143-D, D as in dog,  
12 160-A through 173-A, 190-A through 192-A, and 199-A through  
13 199-B, as in bravo.

14 THE COURT: Those are all the exhibits covered by the  
15 stipulation, correct?

16 MS. MORTAZAVI: Correct, your Honor.

17 MR. FERNICH: No objection from the defense.

18 THE COURT: All right. They'll be received in  
19 evidence.

20 (Government's Exhibits 9011, 101-A through 115-C,  
21 117-A through 143-D, 160-A through 173-A, 190-A through 192-A,  
22 and 199-A through 199-B received in evidence)

23 MS. MORTAZAVI: Your Honor, and I'll read one separate  
24 exhibit dealing with one of those calls. That's Government  
25 Exhibit 9014. It was signed this morning, and I don't believe

M1PPFIS2

Folensbee - Direct

1 the Court has a copy, but I'll be reading it into the record.

2 THE COURT: Slowly, though, okay?

3 MS. MORTAZAVI: Government Exhibit 192-AT is a true  
4 and accurate English-language translation and transcription of  
5 the Spanish-language recording contained in Government  
6 Exhibit 192-A. Government Exhibit 192-AT reflects true and  
7 accurate information regarding voice attributions, time and/or  
8 date, and participating phone numbers for Government  
9 Exhibit 192-A.

10 I will do my best to slow down for the court reporter.

11 And, your Honor, with that stipulation, I'd like the  
12 jurors to please turn to the binders in front of them to the  
13 tab marked 121-AT, and I'd like to have Ms. Jung please pull up  
14 that government exhibit, and please play the portion of the  
15 recording marked Government Exhibit 121-A.

16 THE COURT: All right. Don't play it until I say go  
17 ahead because everyone needs a minute.

18 MS. MORTAZAVI: Certainly, and I'll just state for the  
19 record that this is a portion of an intercepted call taking  
20 place on March 21st, 2019, between Seth Fishman and an  
21 unidentified male, as indicated on Government Exhibit 121-AT.

22 THE COURT: Has everyone found the exhibit? Anyone  
23 need more time? Just raise your hand. Okay. And if it's  
24 easier for you, I do think the exhibit is on your screen.

25 Is right?

M1PPFIS2

Folensbee - Direct

1 MS. MORTAZAVI: That's correct.

2 THE COURT: Is that easier? Does anyone need more  
3 time?

4 JUROR: Can we have more?

5 THE COURT: Can you have more time? Sure. I'm not  
6 hearing.

7 JUROR: Can we have the ones that can't find it in the  
8 book?

9 THE COURT: It's on the screen.

10 JUROR: Oh, okay.

11 THE COURT: Is your screen --

12 JUROR: No, I have it.

13 THE COURT: Thank you.

14 All right. Ms. Mortazavi?

15 MS. MORTAZAVI: Ms. Jung, if you could play Government  
16 Exhibit 121-A.

17 (Audio played)

18 And, your Honor, I'd like to direct the jurors to the  
19 next tab in their binders, what's been marked as Government  
20 Exhibit 121-BT, B as in bravo, and have Ms. Jung please pull up  
21 Government Exhibit 121-BT and Government Exhibit 121-B but not  
22 yet play that portion of a recorded call.

23 And for the jurors' benefit, I'll describe this  
24 particular government exhibit is a portion of that same  
25 intercepted call that we heard, Government Exhibit 121-A, but

M1PPFIS2

Folensbee - Direct

1 occurring later during that call.

2 Ms. Jung, could you please play that recording?

3 (Audio played)

4 And, your Honor, I'll direct the jurors and the Court  
5 to what's been marked as Government Exhibit 121-DT, which is  
6 also in the transcript binder. It is another portion of that  
7 same intercepted call on March 21st, 2019, and I'll ask  
8 Ms. Jung to please ready Government Exhibit 121-D. And it  
9 appears the jurors have located that transcript.

10 THE COURT: Yes.

11 MS. MORTAZAVI: Ms. Jung, if you could play Government  
12 Exhibit 121-D.

13 (Audio played)

14 Thank you, your Honor. And I'd like to direct the  
15 jurors to one more recording and transcript. It's what's been  
16 marked as Government Exhibit 128-AT in their binders, and I'll  
17 have Ms. Jung pull up to the screen Government Exhibit 128-AT  
18 and 128-A.

19 And this is as reflected in the stipulation that I  
20 read for the record, a portion of the intercepted call on  
21 April 25th, 2019, between Seth Fishman and an unidentified  
22 male.

23 Ms. Jung, if you could play Government Exhibit 128-A.

24 (Audio played)

25 Thank you, your Honor.

M1PPFIS2

Bowman - Direct

1 The government would now like to call Dr. Jean Bowman  
2 to the stand.

3 THE COURT: Good morning, Dr. Bowman. Once you're in  
4 the enclosure, you can take your mask off and remain standing.

5 Ms. Dempsey?

6 JEAN BOWMAN,

7 called as a witness by the Government,

8 having been duly sworn, testified as follows:

9 THE COURT: If you can try to speak into the  
10 microphone.

11 THE WITNESS: I do.

12 THE COURT: Please spell and say your last name. You  
13 can be seated.

14 THE WITNESS: My last name is Bowman, B-o-w-m-a-n.

15 DIRECT EXAMINATION

16 BY MS. MORTAZAVI:

17 Q. Good morning, Dr. Bowman.

18 A. Good morning.

19 Q. Would you mind pulling the microphone a little bit closer  
20 to your mouth, just so that we make sure all the jurors are  
21 able to hear you?

22 A. Is that better?

23 Q. That's slightly better. It may have to be uncomfortably.

24 A. Better?

25 THE COURT: Yes, it is. Thank you.

M1PPFIS2

Bowman - Direct

1 Q. Dr. Bowman, can you tell us where you are employed?

2 A. Yes. I'm employed at the FDA Center for Veterinary  
3 Medicine.

4 Q. Is that referred to as FDA CVM?

5 A. Yes.

6 Q. What's your current title?

7 A. I'm a veterinary medical officer.

8 Q. What sort of work do you do as a veterinary medical officer  
9 at the FDA CVM?

10 A. In my current position, I do primarily work on unapproved  
11 animal drugs, and that could involve import, sales of  
12 unapproved drugs from brick and mortar retailers and/or online.

13 Q. Dr. Bowman, does the FDA CVM focus on animal drugs?

14 A. Yes, we do.

15 Q. Are both animal drugs and human drugs regulated by the FDA?

16 A. Yes, they are.

17 Q. Are those regulations identical?

18 A. No, they're not.

19 Q. And --

20 A. They're largely similar but not identical.

21 Q. And during your time at the FDA, have you focused solely on  
22 animal drug regulations?

23 A. Yes.

24 Q. For approximately how long have you worked at the FDA CVM?

25 A. I've worked there 32-and-a-half years.

M1PPFIS2

Bowman - Direct

1 Q. And generally speaking, what is the FDA CVM's mission?

2 A. Our mission is to make sure that there are safe and  
3 effective animal drugs available and keeping human food supply  
4 safe.

5 Q. Are you a licensed veterinarian?

6 A. Yes, I am.

7 Q. What state are you licensed in?

8 A. I'm licensed in Maryland.

9 Q. And what's your educational background?

10 A. I have a Bachelor of Science in animal science from the  
11 University of Maryland, and a DVM from -- it's from Virginia  
12 Tech, but it's the Maryland Virginia Regional College of  
13 Veterinary Medicine. That's a mouthful.

14 Q. It certainly is. You mentioned the acronym DVM. What does  
15 that stand for?

16 A. That stands for Doctor of Veterinary Medicine.

17 Q. Were you employed between college and veterinary school?

18 A. I was, yes.

19 Q. Where?

20 A. I was employed at the University of Maryland Horse Research  
21 Center.

22 Q. What sort of work did you do at the Horse Research Center  
23 at the University of Maryland?

24 A. I did all sorts of work, from general animal care to  
25 collecting samples for studies that professors at the

M1PPFIS2

Bowman - Direct

1 University were doing. We had a breeding herd. We maintained  
2 the foals, mares and teased and bred mares through artificial  
3 insemination.

4 Q. And, Dr. Bowman, I'm just going to ask you, for the benefit  
5 of our court reporter and our jurors, to keep your voice up and  
6 to the extent you can, speak into the microphone.

7 A. Thank you.

8 Q. I know the logistics are a little foreign.

9 And, Dr. Bowman, what year did you begin veterinary  
10 school?

11 A. I began veterinary school in 1985.

12 Q. And what year did you graduate?

13 A. 1989.

14 Q. After you graduated from veterinary school, what did you do  
15 next?

16 A. I started practicing with a veterinarian that I knew doing  
17 farm call, equine practice primarily, and I also, within a few  
18 months, started working at CVM.

19 Q. I'd like to ask you about the farm call/equine practice.  
20 What is the term "farm call"?

21 A. "Farm call" means it is a mobile practice, where you bring  
22 your services to the clients at their homes or the place where  
23 their horse is boarded.

24 Q. And you mentioned equine practice, does that mean that you  
25 focused on horses?

M1PPFIS2

Bowman - Direct

1 A. Yes, it does.

2 Q. How long were you employed in that farm call practice?

3 A. For five years.

4 Q. You mentioned that, in generalities, the sort of work you  
5 did in that practice, can you elaborate as to the tasks that  
6 you engaged in?

7 A. It was all types of routine and emergency veterinary care;  
8 so you might be seeing lacerations or other injuries,  
9 lamenesses, doing routine healthcare such as administering  
10 dewormers or vaccinations, setting up programs for farms so  
11 that they have their horses on a regular schedule to keep them  
12 healthy, maybe colics, every type of routine emergency that  
13 could be seen.

14 Q. Did you conduct physical examinations of horses?

15 A. Yes.

16 Q. Did you prescribes drugs to patients?

17 A. Yes.

18 Q. And have you heard the term "medical file"?

19 A. Yes.

20 Q. Did you maintain medical files for patients?

21 A. Yes, we did.

22 Q. What is a medical file?

23 A. A medical file is the record of the treatment and diagnosis  
24 for each patient.

25 Q. And what types of records would typically be included in a

M1PPFIS2

Bowman - Direct

1 medical files?

2 A. That would include dates of visits, the findings of the  
3 physical exam, any diagnostic tests that were ordered and their  
4 results, and any medications that were prescribed or home  
5 healthcare that was recommended.

6 Q. And you mentioned, Dr. Bowman, that you were employed in  
7 that practice for five years; is that correct?

8 A. That's correct.

9 Q. All right. I believe you mentioned that a few months after  
10 you were on the farm call practice, you then became employed  
11 with the FDA CVM, correct?

12 A. Correct.

13 Q. In what year did you join the FDA CVM?

14 A. I joined in August of 1989.

15 Q. And when you first joined the agency, what position did you  
16 hold?

17 A. I was veterinary medical officer.

18 Q. And what responsibilities did you have when you first  
19 joined the FDA?

20 A. When I first joined the FDA, I was in the office of new  
21 animal drug evaluation, and my duties involved reviewing the  
22 data and helping companies set protocols to test their proposed  
23 new animal drugs for safety and effectiveness.

24 Q. Did you subsequently move to a different position?

25 A. I did. In 2008, I -- it's called "crossing the street"

M1PPFIS2

Bowman - Direct

1 because it's literally crossing the street. I moved into the  
2 office of surveillance and compliance, which is primarily  
3 dealing with post-marketing of animal drugs.

4 Q. And when you refer to surveillance and compliance, what is  
5 that portion of FDA CVM ensuring compliance with?

6 A. Their role is to ensure compliance with the rules and  
7 regulations in the Federal Food Drug and Cosmetic Act.

8 Q. Does the federal Food Drug and Cosmetic Act sometimes  
9 referred to as the FDCA?

10 A. Yes, it is.

11 Q. And is that the office, the office in which you currently  
12 work as a veterinary medical officer?

13 A. Yes, it is.

14 Q. Have you heard the term enforcement action?

15 A. Yes.

16 Q. And what are those?

17 A. In our universe, enforcement actions can be anything from  
18 an advisory letter or a warning letter to a seizure injunction.  
19 When a firm refuses to come into compliance, they might be  
20 enjoined to stop manufacturing certain drugs or stop other  
21 activities.

22 Q. And what sorts of tools does the FDA have to ensure  
23 oversight and compliance by a company?

24 A. Our tools at the center level are somewhat limited. We can  
25 send letters. We can have meetings, and we can -- our top

M1PPFIS2

Bowman - Direct

1 action that I've ever heard of is enjoining a firm to stop  
2 their activities, but we can also refer cases to the office of  
3 criminal investigations part of FDA and, at times, they will  
4 take those cases on.

5 Q. Does the FDA employ FDA agents?

6 A. Yes, they do.

7 Q. Do they conduct investigations?

8 A. Yes.

9 Q. And in your current position, Dr. Bowman, do you have a  
10 particular focus?

11 A. My particular focus is involving unapproved drugs pretty  
12 broadly, but one of my specifics duties is writing GRASE  
13 evaluations, which are determinations of unapproved drugs, to  
14 determine whether they are generally recognized as safe and  
15 effective, and if they, are then they don't require approval  
16 under the act. So that's a type of review that I do quite  
17 often to determine whether drugs are truly unapproved drugs  
18 that needs further evaluation of what are the risks of those  
19 drugs.

20 Q. And, Dr. Bowman, you mentioned the term GRASE. Am I to  
21 take it that's an acronym for Generally Recognized As Safe and  
22 Effective?

23 A. Yes.

24 Q. So your GRASE analysis is reviewing the safety and efficacy  
25 of drugs; is that fair?

M1PPFIS2

Bowman - Direct

1 A. Yes.

2 Q. And apart from the professional experience you just  
3 described with respect to horses, do you have any experience  
4 with horses beyond your professional farm call practice and  
5 your work at the FDA and CVM?

6 A. Yes. I've been a horse owner and enthusiast since I was a  
7 kid. I got my first horse when I was 11, and I still have  
8 three horses for just family use, for my children and I to  
9 enjoy as pleasure horses.

10 Q. Do you race horses?

11 A. No.

12 Q. Have you ever raced horses?

13 A. No.

14 Q. Dr. Bowman, have you testified on behalf of the FDA CVM  
15 before?

16 A. Yes.

17 Q. Have you ever been called as an expert witness before?

18 A. Yes, once before.

19 MS. MORTAZAVI: Your Honor, at this time, the  
20 government offers Dr. Bowman as an expert in FDA and new animal  
21 drug approvals and enforcement process and the standards for  
22 veterinary practice.

23 MR. SERCARZ: No objection, subject to the material  
24 discussed in the in limine practice, your Honor.

25 THE COURT: All right. She will be qualified.

M1PPFIS2

Bowman - Direct

1 MS. MORTAZAVI: Thank you.

2 THE COURT: Recognized as qualified.

3 MS. MORTAZAVI: Thank you, your Honor.

4 BY MS. MORTAZAVI:

5 Q. Dr. Bowman, you mentioned in your prior position as a  
6 veterinary medical officer that you reviewed new animal drugs  
7 and participated in the new animal drug approval process,  
8 correct?

9 A. Correct.

10 Q. What is considered an animal drug?

11 A. An animal -- well, a drug is any substance or article that  
12 is intended to treat a disease or the symptoms of a disease, or  
13 to the affect the structure or function of the animal, or is  
14 found in one of the national pharmacopeias or is a component of  
15 one of those other articles, and that applies to both human and  
16 animal drugs.

17 Q. All right. And, Dr. Bowman, I want to ask you some  
18 follow-up questions about what you just said. You mentioned  
19 that a drug would be anything that could be used in the  
20 treatment or diagnosis of a disease, correct?

21 A. Correct.

22 Q. Could you give an example?

23 A. In the equine world, flunixin meglumine.

24 Q. Could you just spell that for the court reporter?

25 A. F-l-u-n-i-x-i-n, m-e-g-l-u-m-i-n-e. And that's a

M1PPFIS2

Bowman - Direct

1 nonsteroidal anti-inflammatory drug that's used to treat pain,  
2 colic, which is intestinal pain, fevers.

3 Q. So something that is intended to treat pain would be  
4 considered a drug?

5 A. Yes.

6 Q. Okay. And you also mentioned a drug would be anything that  
7 would affect the structure or function of the animal; is that  
8 correct?

9 A. Yes.

10 Q. And could you give an example of that?

11 A. A drug that's intended to strengthen your fingernails or  
12 the horses hoof, that would be considered a drug.

13 Q. Okay. And an animal drug, is that a drug that is intended  
14 for use by animals?

15 A. Yes.

16 Q. All right. Are there also prescription animal drug and  
17 over-the-counter animal drugs?

18 A. Yes.

19 Q. Can you give us an example of a prescription animal drugs?

20 A. The flunixin meglumine that I just mentioned is a  
21 prescription animal drug.

22 Q. All right. And an example of an over-the-counter animal  
23 drug?

24 A. An over-the-counter animal drug is actually Penicillin.

25 Q. Are you familiar with the term API?

M1PPFIS2

Bowman - Direct

1 A. Yes.

2 Q. What does that stand for?

3 A. It stands for active pharmaceutical ingredient.

4 Q. And what is that?

5 A. That's the active ingredient in an animal drug, and there  
6 could be more than one in an animal drug.

7 Q. Can you give us some examples of what would be considered  
8 an API?

9 A. We can go back to the same one, flunixin meglumine is the  
10 API in the product that there's a paste, an oral paste, and  
11 there's also an injection. So that's the established name for  
12 the active ingredient is flunixin meglumine.

13 Q. Have you heard of Erythropoietin?

14 A. Yes.

15 Q. Is that an API?

16 A. Yes.

17 Q. And have you heard of the term opioid?

18 A. Yes.

19 Q. What is an opioid?

20 A. Opioids are a class of pharmaceuticals that act on the  
21 opioid receptors in the body.

22 Q. Would those be considered APIs?

23 A. Yes, they would.

24 Q. What did the FDA CVM look to in determining whether a  
25 substance is, in fact, a drug?

M1PPFIS2

Bowman - Direct

1 A. As opposed to?

2 Q. As opposed to any other substance. In other words, what  
3 does the FDA CVM refer to to conclude that something is an  
4 animal drug?

5 A. If it meets the definition of an animal drug as described  
6 in the act, then it's an animal drug.

7 Q. What sorts of materials or records would indicate whether a  
8 drug would affect the structure or function of an animal, for  
9 example?

10 A. We look at the intended use for products. So descriptions  
11 of the intended use are usually found on the label in the  
12 medication section. Failing that, we would look at published  
13 materials or online information available at the point of sale  
14 that would establish the intended use. That's just what  
15 they -- what the company that's marketing it is telling you  
16 that it's used for.

17 Q. So FDA CVM would look at any labeling for a particular  
18 drug?

19 A. We would look at all the labeling we could find.

20 Q. Okay. Would the FDA CVM also review promotional material?

21 A. Yes.

22 Q. That includes pamphlets, brochures?

23 A. Yes.

24 Q. Things like that?

25 A. Yes.

M1PPFIS2

Bowman - Direct

1 Q. What about statements by the manufacturer?

2 A. Yes. We would look at statements. We have e-mail  
3 exchanges, like e-mails, anything that we can get that helps  
4 establish that intended use is necessary.

5 Q. What about oral representations by the manufacturer?

6 A. Yes.

7 Q. And what about the name of the product?

8 A. Sometimes, yes.

9 Q. To what extent do the actual chemical contents of the  
10 substance matter in determining its intended use?

11 A. That varies on the product. If it's a product that has a  
12 very limited usefulness, then the fact that that chemical is in  
13 there is certainly going to give us evidence towards intended  
14 use.

15 Q. Can the FDA CVM conclude that a product is a drug just by  
16 looking at the materials you referenced earlier, the labeling,  
17 promotional materials, oral statements?

18 A. Yes.

19 Q. Does the FDA have to conduct drug testing before  
20 determining that something is a drug?

21 A. No, not at all.

22 Q. Dr. Bowman, we discussed APIs, active pharmaceutical  
23 ingredients, a moment ago. If a substance contains no APIs,  
24 but the manufacturer claims that it will treat a disease, would  
25 that be considered a drug?

M1PPFIS2

Bowman - Direct

1 A. Yes.

2 Q. And what is considered a new animal drug?

3 A. So a drug is a new animal drug if it's not generally  
4 recognized as safe and effective for the intended use by  
5 experts in the field.

6 Q. You mentioned, Dr. Bowman, that you participated in the new  
7 animal drug approval process at FDA CVM, correct?

8 A. Correct.

9 Q. Can you walk us through, at a high level, that process?

10 A. In that process, companies come into the FDA, they usually  
11 have an idea or a concept product. They come in, they sit down  
12 with us. We set up meetings to help them develop protocols to  
13 prove that the drug is safe and effective, and establish the  
14 recommended types of studies to prove that it will work for the  
15 intended indication. As that process plays out over time, data  
16 is collected, it comes into the FDA, it's reviewed.

17 Q. And, Dr. Bowman, let me stop you there. You said that data  
18 is collected. Can you elaborate on what type of data is  
19 collected, as far of a new animal drug approval process?

20 A. So when we develop those protocols, those protocols are  
21 from multiple studies. Some of the studies are intended to  
22 establish the safety of the product. Some firms come in with a  
23 dose already pretty firmly established. In that case, they may  
24 only need to prove that the dose is safe, and then they go on  
25 to prove that it's also effective for the intended use. So

M1PPFIS2

Bowman - Direct

1 that takes multiple studies in both safety and effectiveness.

2 They also have to go through a manufacturing section,  
3 where they prove that they can manufacture the product and have  
4 it be repeatable; that they can always manufacture it to the  
5 same standard, and all of the ingredients that go into that  
6 product have to come from approved sources. All of that is  
7 done in the pre-approval section of the application.

8 Q. And, Dr. Bowman, are you familiar with clinical trials?

9 A. Yes.

10 Q. Do those play any role in the new animal drug approval  
11 process?

12 A. Yes. A lot of the efficacy data is conducted or collected  
13 in clinical trials.

14 Q. You mentioned that data is collected and then submitted to  
15 the FDA CVM. Is that data from clinical trials that the  
16 manufacturer will have conducted?

17 A. It will be from both laboratory and clinical trials.

18 THE COURT: Ms. Mortazavi, if you can try to find a  
19 convenient time for a break in the next few minutes, that would  
20 be appreciated.

21 MS. MORTAZAVI: Certainly, your Honor. I think I have  
22 a few more questions on this topic, and then I think that will be a  
23 natural breaking point.

24 THE COURT: Great.

25 BY MS. MORTAZAVI:

M1PPFIS2

Bowman - Direct

1 Q. Dr. Bowman, you mentioned the term "safe and effective" a  
2 few times. Can you give us a hypothetical example of a drug  
3 that would be considered ineffective given its intended use?

4 A. I think one of the best examples we have, there are  
5 companies out there that market water, basically, magical water  
6 that's going to treat your cancer. It's not going to do that,  
7 and it's just water, but it's still a drug because the intended  
8 use is to treat cancer.

9 (Continued on next page)

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M1PTFIS3

Bowman - Direct

1 BY MS. MORTAZAVI:

2 Q. And can you give a hypothetical example of a drug that  
3 would be considered unsafe, given its intended use?

4 A. An easy example would be eye medication. If eye medication  
5 isn't sterile and it contains any kind of bacteria or  
6 contaminants, it can seriously damage your eye and cause a  
7 worse problem than you're treating.

8 Q. So when the FDA CVM reviews safety and efficacy, it's  
9 looking to both factors before it will approve the drug, is  
10 that fair to say?

11 A. Yes.

12 Q. How important is the intended use of a drug to the FDA  
13 CVM'S evaluation of whether it's effective?

14 A. It's paramount.

15 Q. Why is that?

16 A. All those studies that are designed are designed to  
17 establish the safety and effectiveness for an intended use. So  
18 that's in the front mind as every study is designed, which  
19 parameters to measure, how frequently to measure those  
20 parameters, how often the follow-ups need to occur, all of that  
21 is protocol development so clinical investigators can conduct  
22 the study and collect uniform data from every patient.

23 Q. So is the intended use of a drug the reference point for  
24 determining whether it's actually effective?

25 MR. FERNICH: Objection.

M1PTFIS3

Bowman - Direct

1 THE COURT: Grounds?

2 MR. FERNICH: Statute speaks for itself.

3 THE COURT: Overruled.

4 Q. Dr. Bowman, you can answer the question.

5 A. Can you repeat it?

6 Q. Sure. Is the intended use of a drug the reference point  
7 for determining whether or not it's effective?

8 A. Yes.

9 MS. MORTAZAVI: Your Honor, that's a good place for us  
10 to pause.

11 THE COURT: All right. We'll take the morning break  
12 now. Since we got started a little bit late, you can try to  
13 keep it to 10, 15 minutes at the most. We might push the lunch  
14 break a little bit further back, but I will see you all in  
15 about 10, 15 minutes.

16 Have a good break.

17 (Continued on next page)

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M1PTFIS3

Bowman - Direct

1 (Jury not present)

2 THE COURT: We'll see everyone back here in about 10,  
3 15 minutes.

4 Dr. Bowman, you remain under oath.

5 THE WITNESS: Thank you.

6 (Recess taken)

7 THE COURT: I understand the jurors are on their way  
8 up.

9 (Continued on next page)

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M1PTFIS3

Bowman - Direct

1 (Jury present)

2 THE COURT: You remain under oath.

3 Ms. Mortazavi, please.

4 MS. MORTAZAVI: Thank you, your Honor.

5 BY MS. MORTAZAVI:

6 Q. Dr. Bowman, before the break we discussed the FDA CVM's  
7 participation in the new animal drug approval process, correct?

8 A. Yes.

9 Q. Does the FDA CVM review both prescription and  
10 over-the-counter new animal drugs?

11 A. Yes, we do.

12 Q. What are the differences, if any, in approving a  
13 prescription animal drug versus an over-the-counter animal  
14 drug?

15 A. The process of getting the drug approved is the same  
16 regardless of whether it is intended for prescription or  
17 over-the-counter status. At times we don't determine the final  
18 marketing status for the drug until all the data is collected  
19 and reviewed, and a drug that might initially be thought of as  
20 likely to be over the counter isn't, the data doesn't show that  
21 it's safe that way, so it may be approved as a prescription  
22 drug instead.

23 Q. And you previously testified that as part of the new animal  
24 drug approval process the FDA CVM will also review  
25 manufacturing conditions, is that right?

M1PTFIS3

Bowman - Direct

1 A. Yes, absolutely.

2 Q. Why does an applicant have to make a showing with respect  
3 to the FDA CVM with respect to how they manufacture a drug?

4 A. They have to be able to manufacture the drug to the same  
5 standard in every batch, and if they can't do that then that  
6 drug is not ready for approval.

7 Q. Does that ensure consistency?

8 A. It ensures consistency from batch to batch and safety from  
9 batch to batch in terms of impurities and maybe microbial  
10 contamination. All of that has to be evaluated and very strict  
11 processes put into place individually for each drug that's  
12 approved.

13 Q. And you testified previously that the suppliers to a drug  
14 manufacturer also have to comply with good drug manufacturing  
15 processes, is that accurate?

16 A. That is accurate.

17 Q. Have you heard the term CGMP?

18 A. Yes.

19 Q. What does that refer to?

20 A. It's the Current Good Manufacturing Practices that the FDA  
21 puts out.

22 Q. Can you explain what those are?

23 A. Those are the general standards by which all drugs need to  
24 be manufactured. And there's different standards for different  
25 types of drugs, so tablets have a different set of standards

M1PTFIS3

Bowman - Direct

1 for their manufacturing than an IV injection. So there's a  
2 series of actual CGMPs depending on the type of drug.

3 Q. Assuming a manufacturer is not in compliance with those  
4 standards, how would that impact the approval process?

5 A. They can't be approved if they're not in compliance.

6 Q. What measures does the FDA CVM take to ensure that a  
7 manufacturer is in compliance?

8 A. Well, as I said, there's an entire technical section  
9 devoted to manufacturing for every new animal drug application,  
10 and in that section they have to detail the entire process from  
11 start to finish, they have to identify and name every component  
12 manufacturer, and all of those component manufacturers have to  
13 be FDA establishment registered and they get inspected before  
14 the drug is approved, as well as the manufacturing facility  
15 that makes the drug at the end, the finished managed  
16 pharmaceutical. So every active component has to meet FDA  
17 standards.

18 Q. And you mentioned, Dr. Bowman, that the components have to  
19 be manufactured consistent to FDA CVM standards, is that right?

20 A. That is correct.

21 Q. By "components," do you mean the final ingredients that go  
22 into the final drug?

23 A. I do, and even the containers.

24 Q. And you also mentioned the suppliers of those components  
25 have to be FDA establishment registered. What does that mean?

M1PTFIS3

Bowman - Direct

1 A. Under the federal Food, Drug & Cosmetic Act, all  
2 manufacturers have to register with FDA, and being part of that  
3 registration process enables FDA to know where they are, what  
4 is made at their facilities, and allows for routine  
5 inspections. So that's all part -- every component of that  
6 drug has to come in under FDA authority.

7 Q. And as part of the new animal drug approval process, is  
8 there any role that the FDA CVM plays in reviewing labeling for  
9 a drug?

10 A. Yes.

11 Q. Can you describe that?

12 A. There's another technical section in the application that  
13 is devoted entirely to labeling, and that will include any  
14 promotional materials that expected to be released along with  
15 the product. It will include the labels themselves, the  
16 cartons, the container labels, any package inserts that are  
17 required.

18 You will notice -- I'm sure you noticed on your drugs,  
19 even over-the-counter drugs, that sometimes there's a kind of  
20 extra label where you unstick and unfold and they have all this  
21 extra information and then you can stick it back on there.  
22 Those are basically the package insert. So a vial or a bottle  
23 that comes inside of a box will have that information often on  
24 a separate sheet of paper that's called a package insert, it  
25 will be inserted in that box.

M1PTFIS3

Bowman - Direct

1 Q. Does the FDA CVM review those materials?

2 A. All of those. They all have to comply.

3 Q. And that is a component of the new drug approval process,  
4 correct?

5 A. Yes, it is.

6 Q. Are there any differences in the standards for labeling for  
7 over-the-counter versus prescription drugs?

8 A. There are some slight differences. Most of the information  
9 is very similar, but on the over-the-counter drugs, first of  
10 all, it won't have the prescription legend, which is that  
11 statement that says: Caution, federal law restricts this drug  
12 to use by only order of a licensed veterinarian, or physician  
13 in the case of a human drug. That won't be on there.

14 It also has to be able to provide directions for use  
15 for the lay person, so the directions for use will read a  
16 little differently. The indications will be easy to  
17 understand, they will be something that any owner can read for  
18 their horse or dog or whatever they're medicating and know  
19 that, okay, my dog has a bald spot and this is to put on bald  
20 spots. So it would be written at a simple level. It won't  
21 give you all the pharmacokinetics of how that drug is absorbed,  
22 it won't give you that stuff, it will be on the prescription  
23 labeling.

24 Q. You mentioned for over-the-counter drugs there is  
25 information given for the lay person to understand, is that

M1PTFIS3

Bowman - Direct

1 right?

2 A. Correct.

3 Q. What do you mean by "lay person?"

4 A. I mean a non-veterinarian.

5 Q. Sort of an average person without medical training?

6 A. Yes.

7 Q. And the labeling information for a particular drug, would  
8 that be included with every bottle of a drug that is  
9 manufactured and distributed?

10 A. Yes.

11 Q. Can oral instructions replace the labeling information that  
12 you just described?

13 A. No.

14 Q. So I would like to ask you a hypothetical question  
15 Dr. Bowman, based on the answers that you have given. If a  
16 veterinarian were to ship a client a drug with no label but  
17 provide instructions for the drug's use over the phone, would  
18 that be sufficient to satisfy labeling requirements?

19 A. No.

20 MR. FERNICH: Objection. I could approach.

21 THE COURT: I will see counsel at the sidebar.

22 (Continued on next page)

M1PTFIS3

Bowman - Direct

1 (At sidebar)

2 MR. FERNICH: Just briefly, under Second Circuit  
3 authority like Scop, S-C-O-P, and Garcia, hypotheticals that  
4 track the facts of the case posed to an expert are unhelpful  
5 and impermissible and merely tell the jury what result to  
6 reach. They're improper bolstering.

7 MS. MORTAZAVI: Your Honor, we're not going to ask the  
8 expert for her ultimate conclusion as to the facts the jury  
9 will find, my hypothetical was asked to the labeling  
10 requirement, which I think she is permitted to opine on.

11 THE COURT: Let me go back and look at the question.

12 (Pause)

13 THE COURT: The objection is overruled.

14 (Continued on next page)

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M1PTFIS3

Bowman - Direct

1 (In open court)

2 THE COURT: The objection is overruled.

3 Dr. Bowman, you may answer, the question but could we  
4 have the question read back.

5 (Record read)

6 A. No.

7 Q. Why is that?

8 A. The minimum labeling requirements have to be in writing for  
9 people to refer back to. A phone conversation to provide  
10 additional context is great, but they still need that written  
11 material to refer back to in case they're not administering it  
12 at the moment. If they're speaking to the vet or the person on  
13 the phone, they need something that they can look at and say we  
14 give this as an injection or give this as oral.

15 Q. Thank you. Dr. Bowman, you referenced tracking that the  
16 FDA CVM does for manufacturers. What, if any, records does the  
17 FDA CVM maintain for approved animal drugs?

18 A. For approved animal drugs we have a database that we  
19 maintain. You can access that information publicly at animal  
20 drugs at FDA, I think it is, I forget the exact address, but  
21 Google that and it will pop right up.

22 THE COURT: Don't Google that.

23 A. That allows everyone to see what is approved and what the  
24 concentrations of the ingredients are and the information on  
25 what it's used for, what it's indicated for, what species, what

M1PTFIS3

Bowman - Direct

1 doses, what conditions.

2 Q. In the new animal drug approval process, how important is  
3 the identity of the manufacturer?

4 A. It's extremely important because at any point that the --  
5 we call the person who gets the drug approved the drug sponsor.  
6 So at any point if the drug sponsor -- maybe they can no longer  
7 get an ingredient for their formulation from the original  
8 source, they actually have to file a supplemental approval to  
9 get a new source approved. Or if they have to change  
10 locations, maybe they have a fire and their building burns  
11 down, they can't just hire another company to make their drug,  
12 they have to actually get a new location approved, it has to be  
13 inspected, we have to make sure that they can actually follow  
14 the process that is outlined in their application at that  
15 location to manufacture the drug so it will be the same as it  
16 was before.

17 Q. Dr. Bowman, I can't speak to the jurors sitting in the  
18 back, I'm having a little bit of difficulty hearing you. If  
19 you could pull microphone even closer.

20 A. Okay.

21 Q. I think you may be able to pull it down as well.

22 A. Yep.

23 Q. Thank you.

24 So Dr. Bowman --

25 THE COURT: Let me interrupt at this point. If at any

M1PTFIS3

Bowman - Direct

1 time any of you can't hear, please raise your hand or wave me  
2 down so we'll ask to make the necessary adjustments. It's very  
3 important that you be able to see and to hear.

4 Thank you all.

5 MS. MORTAZAVI: Your Honor, it may be the plexiglass  
6 that's making it harder.

7 THE COURT: Could be.

8 Q. Once a drug is approved, could any company manufacture that  
9 approved drug?

10 A. No.

11 Q. Why not?

12 A. That approved drug is the property of the company that  
13 sponsored it and got it approved.

14 Q. Can the sponsor that put forward the new animal drug for  
15 approval change the ingredients of that drug without consulting  
16 with the FDA CVM?

17 A. No.

18 Q. Why not?

19 A. Because a change in ingredients could charge the  
20 effectiveness or the safety of the drug.

21 Q. And what about the intended use of the drug?

22 A. The intended use of the drug, if the company wants to  
23 modify their application to add an intended use, that requires  
24 a supplemental application with additional data to support that  
25 new use.

M1PTFIS3

Bowman - Direct

1 Q. After a new animal drug is approved, does the FDA CVM's  
2 oversight of that company or that drug end?

3 A. No. The companies file annual reports that include the  
4 amount of the drug that they sold during the year, they include  
5 any reports of adverse events that have come in to them, which  
6 their contact information is right on the label, so that, for  
7 adverse reporting purposes, they're required by law to submit  
8 all those adverse events to us.

9 Q. Dr. Bowman, if I could pause you there, you mentioned  
10 adverse events, could you just explain what you mean by that  
11 term?

12 A. So an adverse event is an unanticipated negative  
13 consequence that is attributed to the drug. It may not  
14 actually be the fault of the drug, but if it happened at the  
15 time that the drug was being administered, a lot of people will  
16 assume that the drug caused it. So all of those should be  
17 reported and they will all get investigated by our team that  
18 specializes in that.

19 Q. And the reporting of adverse events, is that part of the  
20 annual report that you mentioned?

21 A. It is, unless there are serious adverse events which have  
22 to be reported more frequently.

23 Q. And does the FDA CVM take action in response to a series of  
24 adverse events for a particular drug?

25 A. Yes.

M1PTFIS3

Bowman - Direct

1 Q. What sorts of things does the FDA CVM do?

2 A. The FDA may encourage a firm to do a recall. Recalls are  
3 technically voluntary, but we can encourage firms to do that.  
4 In other cases, we may need to modify the labeling. So if we  
5 see a frequently occurring adverse event and we can anticipate  
6 changes in the process of selecting the patients or maybe  
7 administering the drug that would ameliorate those risks, we  
8 will have the label changed to make that safer.

9 Q. Dr. Bowman, apart from the annual reporting that you just  
10 described, are there any other ways in which FDA CVM engages  
11 with a drug manufacturer after approval?

12 A. There are routine inspections of the manufacturing  
13 facilities that happen following approval. Every one to two  
14 years generally there's new inspections to ensure that they're  
15 continuing to follow the process laid out in their application.

16 Q. Dr. Bowman, I would like turn to a prior discussion of  
17 prescription drugs and over-the-counter drugs. Can you tell us  
18 what is the difference between a prescription drug and an  
19 over-the-counter drug?

20 A. So an over-the-counter drug is one, just like on the human  
21 side, that you can walk into -- instead of a pharmacy it will  
22 often be a tack store or a feed store, and it will just be  
23 sitting there on the shelf and you can just purchase it for  
24 use.

25 A prescription drug will either be dispensed by your

M1PTFIS3

Bowman - Direct

1 veterinarian at the time that they examine your pet or your  
2 animal and make a diagnosis and recommended treatment or they  
3 may give you a written prescription which you can take to  
4 another pharmacy to get filled.

5 Q. And Dr. Bowman, by "dispense," do you mean a veterinarian  
6 will actually administer, either by injection or orally, the  
7 drug itself?

8 A. Sometimes it would be administration of the drug, but  
9 generally it will be maybe the veterinarian shows you how to  
10 give the first dose and then they hand you the bottle and say  
11 you're going to continue this medication for the next ten days,  
12 do it exactly as I just showed you but do it twice a day for  
13 the next ten days, for example.

14 Q. And you testified that the FDA CVM, as part of the new  
15 animal drug approval process, will look to whether something  
16 should -- a drug should be prescription or over the counter,  
17 correct?

18 A. Correct.

19 Q. What sorts of things does the FDA CVM look to to make that  
20 determination?

21 A. Well, I think the primary cutoff is if directions for use  
22 can be written for the laymen the way the law is written then  
23 the drug should be over the counter.

24 However, we look at -- when you're looking at the drug  
25 we're also looking at: How safe is it? Is the therapeutic

M1PTFIS3

Bowman - Direct

1 window really narrow? That's the difference between the  
2 effective dose and the toxic dose. If that window is really  
3 narrow, then you don't allow that to be an over-the-counter  
4 drug, that should be a prescription drug. Somebody should  
5 calculate that dose who you can rely on to calculate it  
6 correctly.

7 Other things that might put it into the prescription  
8 category would be the route of administration. So if a drug  
9 requires IV administration, it will be prescription, because  
10 most owners don't have the skill necessary to administer an IV  
11 injection.

12 Q. Dr. Bowman, by IV, do you mean intravenous?

13 A. I do, I'm sorry, intravenous injection.

14 Q. What does that refer to in layman's terms?

15 A. It's an injection directly into the vein. So if it  
16 requires injection directly into the vein, that's a skill that  
17 veterinarians learn but most owners do not -- are not  
18 proficient and could not do that. A lot of times drugs are  
19 administered IV because they're very damaging to the muscle  
20 tissue if you get them outside the vein. So there's usually a  
21 reason why those drugs are administered IV.

22 Q. There's other routes?

23 A. There's other routes of administration that also require  
24 prescription status, such as drugs that are delivered via  
25 nasogastric tube where you pass a tube down to the animal's

M1PTFIS3

Bowman - Direct

1 stomach and administer the drug through the tube. That will  
2 require prescription status.

3 Q. Dr. Bowman, are there oral drugs, so drugs you would take  
4 through your mouth, that are still prescription status?

5 A. Oh, yes, many. Most antibiotics and any drugs -- like I  
6 said, if it requires a diagnosis prior to use, if the pet owner  
7 or the horse owner can't make that diagnosis because they don't  
8 have the training, the skills, or the diagnostic tests, then  
9 that drug is going to be prescription only because veterinarian  
10 has to make that diagnosis before determining that drug is  
11 appropriate for that patient.

12 Q. So the method of administration and the therapeutic window  
13 that you testified about are two of many factors that go into  
14 FDA CVM's determination of deeming something prescription or  
15 over the counter, is that fair to say?

16 A. Yes.

17 Q. Dr. Bowman, are you familiar with the term IM injection?

18 A. Yes, that's intramuscular injection.

19 Q. What does that mean?

20 A. There's many kinds of injections. Intramuscular injections  
21 are the kind where the needle is directed into a muscle mass  
22 before the liquid is injected into the animal.

23 MS. MORTAZAVI: Ms. Jung, if you could please pull up  
24 but not yet play Government Exhibit 139A. And I would like to  
25 direct the jurors to their binders to the tab marked 139AT.

M1PTFIS3

Bowman - Direct

1 And I will also have Ms. Jung pull up that exhibit.

2 THE COURT: This is in evidence?

3 MS. MORTAZAVI: That's correct, your Honor, that was  
4 subject to the prior stipulation.

5 While the jurors are finding their place in the  
6 binder, I will remark this is a portion of an intercepted call  
7 dated June 4, 2019, between Seth Fishman and Lisa Giannelli, as  
8 indicated on Government Exhibit 139AT.

9 Ms. Jung, if you could please play Government  
10 Exhibit 139A.

11 (Audio recording played)

12 MS. MORTAZAVI: I will ask the jurors to please put  
13 away their binders.

14 BY MS. MORTAZAVI:

15 Q. Dr. Bowman, are you familiar with the concept of  
16 nutritional supplements for humans?

17 A. Yes.

18 Q. Generally speaking, what are nutritional supplements for  
19 human use?

20 THE COURT: Let's pause for a moment and let everyone  
21 get settled. These binders are bulky.

22 You want to repeat the question, Ms. Mortazavi?

23 MS. MORTAZAVI: Of course.

24 Q. Generally speaking, Dr. Bowman, what does the term  
25 nutritional supplements for humans refer to?

M1PTFIS3

Bowman - Direct

1 A. It's a more recent category of FDA-regulated products that  
2 are allowed to make some structure function claims without  
3 having to go through the drug approval process.

4 Q. Is that category of nutritional supplements something that  
5 the FDA CVM recognizes for animals?

6 A. No, the FDA CVM's type animal drugs in general were not  
7 included in the act that established that category of drugs for  
8 people. That's called DSHEA. I couldn't tell you what DSHEA  
9 stands for right this minute, but that's an act that was  
10 enacted that left animals out.

11 Q. So is there any category of nutritional supplements that is  
12 approved for animal use?

13 A. In general, products that make structure function claims  
14 are either foods for us or they're drugs.

15 Q. So with respect to FDA CVM's classifications, it's a food  
16 or it's a drug, correct?

17 A. Correct.

18 Q. Dr. Bowman, I would like to shift and ask you about your  
19 experiences in veterinarian practice. Are you familiar with  
20 the term VCPR?

21 A. Yes.

22 Q. What does that term refer to?

23 A. VCPR is the acronym for Veterinarian-Client Patient  
24 Relationship, and that is the structure under which animals are  
25 properly treated and diagnosed. So you have a relationship

M1PTFIS3

Bowman - Direct

1 with your veterinarian, you and your veterinarian work together  
2 to ensure the health of that animal that's in your care.

3 Q. Dr. Bowman, in that relationship, who is the client?

4 A. The client is typically the owner, but in some cases the  
5 client may be whoever is designated by the owner to have  
6 decision-making authority for that animal.

7 Q. Who is considered the patient?

8 A. The patient is the animal.

9 Q. What sorts of steps would have a veterinarian take in order  
10 to establish that relationship?

11 A. The veterinarian would have to meet with the client and the  
12 pet or the horse, whatever animal it is, and examine that  
13 animal, establish its current health conditions, whether it has  
14 any chronic problems, and what the goals are for the visit. Is  
15 the animal sick at that moment? Is it just getting caught up  
16 on routine? Is it just having an annual physical? Like all of  
17 us go in for annual physicals, people establish annual  
18 physicals for their animals as well. And that is the first  
19 step in establishing that relationship.

20 Q. And typically speaking, in that relationship, who is  
21 qualified to issue prescriptions for a prescription animal  
22 drug?

23 A. The veterinarian.

24 Q. And before issuing a prescription, what steps does the  
25 veterinarian typically take?

M1PTFIS3

Bowman - Direct

1 A. Typically the veterinarian needs to examine the animal,  
2 establish a diagnosis, discuss that with the owner, create a  
3 treatment plan and a follow-up plan. If there's any diagnostic  
4 test that needs to be completed in order to make that final  
5 diagnosis. You may make a preliminary diagnosis, but you may  
6 need some diagnostic test to confirm it and then decide what  
7 drug to administer to treat that problem that you diagnosed.

8 Q. Those steps that you just described, are those the same  
9 whether a patient is a new patient or an existing patient?

10 A. Generally they're the same for a new problem. If it's an  
11 existing problem in an existing patient, so you're already  
12 familiar with the patient and the owner, and the problem is  
13 chronic, it may not require a new physical exam every time that  
14 you recommend that the client retreat for a chronic problem.

15 Q. You testified about the steps that a veterinarian would  
16 take to reach to a diagnosis. Why would a veterinarian need to  
17 reach a diagnosis before issuing a prescription?

18 A. You don't know what you're treating until you have a  
19 diagnosis, so the diagnosis is important. You may have a lame  
20 horse but you can't just administer a pain reliever without  
21 knowing why the horse is lame and what it really needs to heal.  
22 So you have to examine that horse, and it there could be a  
23 hundred reasons why that horse is lame, and if you don't kind  
24 of drill down to the exact one then you're not actually  
25 treating the problem.

M1PTFIS3

Bowman - Direct

1 Q. Dr. Bowman, you referred a few times to a horse being lame  
2 or lameness, could you just explain what you mean by that?

3 A. A horse that limps. Horses quite often will sustain  
4 injuries that will make them limp. They could be temporary.  
5 They could be chronic. And until you have done that initial  
6 examination and narrowed it down and diagnosed the underlying  
7 problem that's making that horse limp, then you don't know what  
8 you're treating.

9 Q. Is a horse that's lame a horse that's having difficulty  
10 walking?

11 A. It's going to have an abnormal gait when it walks. There's  
12 all sorts of degrees of lameness. So it may not be what we  
13 call hopping lameness where it won't bear any weight on the  
14 leg, it may be just a little gimpy, as we call it.

15 Q. All right. Can a veterinarian establish the  
16 veterinarian-client patient relationship without ever  
17 physically examining an animal?

18 A. No.

19 Q. What if a client describes symptoms to a veterinarian over  
20 the phone but there's no physical examination?

21 A. Unless -- as I said, unless it's a chronic problem that's  
22 been treated multiple times that's expected to recur, then  
23 there's no way to trust that the client's description of the  
24 symptoms will lead you to a diagnosis.

25 Q. What do you mean by that?

M1PTFIS3

Bowman - Direct

1 A. Go back to the lameness example. The horse is lame. Some  
2 horses have chronic lamenesses, like conditions called  
3 navicular disease. Those horses are lame a lot. And you might  
4 consult with your veterinarian by telephone and say Frosty is  
5 lame again, just like always, and the veterinarian may say  
6 okay, let's treat him with a non-steroidal antiinflammatory  
7 drug for five days. If he's not better give me a call, or if  
8 he gets any worse, call me and I will come out. And that's  
9 within that established veterinarian-client relationship.  
10 However, if Frosty is not usually lame and Frosty comes into  
11 the barn lame, then you set up an appointment right away to  
12 check Frosty over to figure out what is going on.

13 Q. Can a veterinarian make a diagnosis based solely from blood  
14 tests without any physical examination?

15 A. No.

16 Q. Why not?

17 A. Because all diagnostic tests have to be interpreted in  
18 light of the physical examination findings and the history  
19 provided by the client.

20 Q. Dr. Bowman, have you heard the term "companion animal?"

21 A. Yes.

22 Q. What does that refer to?

23 A. In the CVM world, companion animals are horses, dogs and  
24 cats. They're basically not for food.

25 Q. And approximately when did the FDA begin to categorize

M1PTFIS3

Bowman - Direct

1 horses, dogs and cats as companion animals?

2 A. To the best of my recollection, it started in the 1990s.

3 Q. Are cattle considered companion animals?

4 A. No.

5 Q. Sheep?

6 A. No.

7 Q. Pigs?

8 A. No.

9 Q. And why does the FDA distinguish between companion animals  
10 and other types of animals?

11 A. The distinction comes during the approval process, because  
12 all the animals that could get used for food, any drug being  
13 approved for their use has to go through an extra step to  
14 determine the human food safety and establish a withdrawal time  
15 so that that drug will be gone from the edible tissues of that  
16 animal. Whether it's milk from a dairy cow, eggs from a  
17 chicken or meat, we want to ensure that that food is safe.

18 Q. Is it typical in a veterinary practice to distribute bulk  
19 quantities of drugs?

20 A. No.

21 Q. Are veterinarians exempted from FDA's regulations regarding  
22 drug manufacturing?

23 A. No.

24 Q. What are the differences between a drug manufacturer and a  
25 veterinarian?

M1PTFIS3

Bowman - Direct

1 A. The job of the drug manufacturer is to manufacture and  
2 distribute quantities of drugs. The job of the veterinarian is  
3 to diagnose and treat animals. And as part of that practice,  
4 veterinarians are allowed to compound for individual patients,  
5 but that requires that they meet the guidance under 21 CFR 530,  
6 which spells out when compounding is appropriate. In general,  
7 they need to use an FDA-approved drug whenever possible as the  
8 starting material for that, and it has to be done only to  
9 prevent animal suffering or death.

10 Q. And do compounded drugs also require prescription before  
11 they can be given out?

12 A. If you are compounding a drug within your practice for an  
13 animal that you already have an established VCPR for, you would  
14 dispense the drug to the patient. You wouldn't write a special  
15 prescription. If they were going to a compounding pharmacy to  
16 get a special drug made for their pet or their horse, then you  
17 would write a prescription that they then could take to a  
18 pharmacy and have filled.

19 Q. You testified before that you have participated in what you  
20 termed GRASE analyses, correct?

21 A. Correct.

22 Q. And that terms refers to Generally Recognized As Safe and  
23 Effective, is that right?

24 A. Correct.

25 Q. Can you explain to us what steps you take when you conduct

M1PTFIS3

Bowman - Direct

1 a GRASE review?

2 A. When we do the GRASE review we review the labeling that's  
3 available to establish the intended use for the drugs.  
4 Typically these are -- well, exclusively these are done on  
5 unapproved animal drugs. The human side of the FDA also does  
6 an analysis like this for their unapproved human drugs. That  
7 analysis, once we have established the intended use, allows us  
8 to search the public literature to see if there are adequate  
9 and well-controlled studies -- as would be required for  
10 approval -- out there that we can look at to see if this drug  
11 is safe and effective for that intended use.

12 Q. Dr. Bowman, do you look to a single publication?

13 A. No, we use databases that include thousands of  
14 publications.

15 Q. Do you also review whether or not a drug appears in an FDA  
16 database?

17 A. Yes, we always -- if it hasn't already been established,  
18 when I do GRASEs I search our internal database to determine  
19 whether the drug has ever had an investigational file or is an  
20 approved new animal drug.

21 Q. Do you also determine whether the manufacturer is  
22 registered with the FDA?

23 A. Yes.

24 MS. MORTAZAVI: Your Honor, I would to like to read  
25 into the record Government Exhibit 9002, which is a stipulation

M1PTFIS3

Bowman - Direct

1 between the parties. If I could have Ms. Jung please pull that  
2 up.

3 THE COURT: All right.

4 MS. MORTAZAVI: With the Court's permission I will  
5 read from the stipulation.

6 THE COURT: Yes.

7 MS. MORTAZAVI: If called to testify at trial,  
8 representatives of the Food & Drug Administration, Center for  
9 Veterinary Medicine, FDA, would testify that after conducting a  
10 diligent search of all relevant records and databases, the FDA  
11 has no records indicating that the FDA issued export  
12 certificates for any of the following companies, individuals  
13 entities or drug products: Equestology, Equestology, Inc.,  
14 Equestology LLC, Seth Fishman, DVM, 21st Century Biochemicals,  
15 Inc., Jordan Fishman, Equiformance, Equiscience, Equi-Tech,  
16 Specialized Performance Compounds, VO2 Max, BB2, BB3 -- and for  
17 the court reporter that's Bravo Bravo -- Serenity, TB-7  
18 (Thymosyn Beta), ITPlus, BPB, HP Bleeder, HP Bleeder Plus,  
19 Homeopathic Bleeder Paste, EPM Double Kill, Iron Sucrose, GNRH,  
20 PSDS (Pain Shot DS), ACTH.

21 After conducting diligent search of all relevant  
22 records and databases, the FDA has no records indicating that  
23 any of the following companies, entities or individuals were  
24 ever registered with the FDA to manufacture drugs in the United  
25 States: Equestology, Inc., Equestology LLC, Seth Fishman, DVM,

M1PTFIS3

Bowman - Direct

1 21st Century biochemicals, Inc., Jordan Fishman, Equiformance,  
2 Equi-Science, Equi-Tech, Specialized Performance Compounds.

3 After conducting a diligent search of all relevant  
4 records and databases, the FDA has no records indicating that  
5 any of the following drug products were listed with the FDA:  
6 VO2 Max, BB2, BB3, Serenity, TB-7 (Thymosyn Beta), ITPlus, BPB,  
7 HP Bleeder, HP Bleeder Plus, Homeopathic Bleeder Paste, EPM  
8 Double Kill, Iron Sucrose, GMRH, PSDS (Pain Shot DS), ACTH.

9 It is further stipulated and agreed by and between the  
10 parties that this stipulation, which is Government  
11 Exhibit 9002, may be received in evidence at trial.

12 And the government offers Government Exhibit 9002.

13 THE COURT: It will be admitted.

14 (Government's Exhibit 9002 received in evidence)

15 MS. MORTAZAVI: Thank you.

16 BY MS. MORTAZAVI:

17 Q. Dr. Bowman, were you asked to conduct GRASE analyses as  
18 part of -- in connection with your testimony in this case?

19 A. Yes, I was.

20 Q. Were you also asked to check whether certain of those drugs  
21 received any FDA approvals?

22 A. Yes.

23 Q. And who asked you to undertake this analysis?

24 A. You did.

25 Q. I would like to review some categories of medications with

M1PTFIS3

Bowman - Direct

1 you and then discuss the analysis that you conducted in this  
2 case.

3 MS. MORTAZAVI: Your Honor, given it's 12:20, I'm  
4 going to proceed, but if the Court would like to break now, it  
5 would be a natural breaking point.

6 THE COURT: Let me talk to Ms. Dempsey.

7 (Pause)

8 THE COURT: I think we should continue because we took  
9 the morning break a little bit late, we got started a little  
10 late, let's press on to at least 12:45 or so.

11 MS. MORTAZAVI: Certainly, your Honor.

12 I would like to admit Government Exhibits 700 to 715.  
13 These are items that were the subject of Government  
14 Exhibit 9008, a stipulation between the parties, and they  
15 represent electronic extractions from a computer that was  
16 seized at Lisa Giannelli's residence.

17 THE COURT: And this stipulation stipulates to these  
18 exhibits and their admissibility?

19 MS. MORTAZAVI: That's correct.

20 THE COURT: They will be admitted.

21 (Government's Exhibits 700 to 715 received in  
22 evidence)

23 MS. MORTAZAVI: Thank you, your Honor.

24 Ms. Jung, please pull up Government Exhibit 711. And  
25 you can publish that to the jurors as it's now in evidence.

M1PTFIS3

Bowman - Direct

1 BY MS. MORTAZAVI:

2 Q. Dr. Bowman, I would like to review this document with you,  
3 which consists of a list of different drugs.

4 Looking at that first category, HP Bleeder Plus,  
5 beside the number 1, could you read the description of this  
6 drug, starting with the first paragraph?

7 A. Yes. A combination of a proven and test-free bleeding  
8 (EIPH: Exercise-Induced Pulmonary Hemorrhage) and analgesic.  
9 The analgesic constituents have been published as effective and  
10 safe in a peer-reviewed study in global journals. Made of a  
11 combination of naturally-occurring amino acids, they are not  
12 easily sourced in their proper enantiomorphs.

13 Q. I would like to ask you some questions about some of the  
14 terms appearing here. Are you familiar with EIPH,  
15 Exercise-Induced Pulmonary Hemorrhage?

16 A. Yes.

17 Q. Can you explain what that refers to?

18 A. It refers to a condition in horses where certain horses  
19 will bleed into their lungs after extreme exercise.

20 Q. And the term "analgesic," are you familiar with that term?

21 A. Yes.

22 Q. What does that mean?

23 A. So an analgesic is a pain killer. In humans, analgesics  
24 are things like aspirin and ibuprofen. There are many in  
25 horses, too.

M1PTFIS3

Bowman - Direct

1 Q. In that second sentence of this description it refers to  
2 the analgesic constituents. What does that mean?

3 A. I presume that that means that the active ingredients that  
4 they're using as an analgesic have been published somewhere as  
5 potentially effective.

6 Q. Could you read the second paragraph under this description  
7 of HP Bleeder Plus.

8 A. Evidence of EIPH can be found in all horses engaged in  
9 strenuous exercise. Racing most notable and although most  
10 diagnostic evidence is subclinical, the overall performance is  
11 always affected. Pressure within pulmonary vasculature  
12 increases nearly three to fourfold during racing. Heart rate  
13 rises and peripheral vasculature constricts causing more  
14 resistance and more work for the heart.

15 Q. There are references here to vasculature. Could you  
16 explain what that means, if you're familiar with that term?

17 A. The vasculature is just referring to veins and arteries.

18 Q. And at the third paragraph, if you could please read the  
19 first two sentences.

20 A. HP Bleeder Plus contains the strongest test-free  
21 vasodilators available on the market. Vasodilation is a  
22 benefit to all athletes, as shown in numerous published  
23 articles for humans.

24 Q. Are you familiar with the term "vasodilator?"

25 A. Yes.

M1PTFIS3

Bowman - Direct

1 Q. What does that mean?

2 A. A vasodilator is a substance that will -- there is smooth  
3 muscle around your veins and your arteries, and that smooth  
4 muscle constricts causing vasoconstriction. That happens when  
5 the horse is exercising to its full extent. It happens in  
6 other situations as well. And it particularly happens in  
7 peripheral -- it starts peripherally, it starts to constrict.  
8 So these drugs would be expected to relax that smooth muscle,  
9 allow the blood to continue to flow into those areas where  
10 oxygen can then be gotten from the blood into the muscle.

11 Q. So does the vasodilator increase blood flow and the flow of  
12 oxygen?

13 A. To the peripheral tissues in this case is how I understand  
14 it.

15 Q. Could you read the last sentence of that same paragraph,  
16 starting with: HP Bleeder Plus can.

17 A. HP Bleeder Plus can achieve same results without the side  
18 effects of Lasix.

19 Q. Are you familiar with Lasix?

20 A. Yes.

21 Q. What is it?

22 A. Lasix is a drug that contains furosemide, and it is --  
23 yeah, it makes you pee a lot, going brain dead here. So it  
24 reduces the circulating volume of fluid.

25 Q. And is furosemide an API or FDA approved drug?

M1PTFIS3

Bowman - Direct

1 A. There is an FDA approved drug. Lasix is FDA approved.

2 Q. And so is furosemide the active ingredient in that drug?

3 A. Yes, it's the established name for the active ingredient.

4 Q. Are there claims here made in the description about the  
5 drug's intended use?

6 A. Yes.

7 Q. What are those?

8 A. It claims to treat EIPH. It claims to cause vasodilation  
9 and to be as effective as the approved drug Lasix.

10 Q. And looking at this description, is this the type of drug  
11 that would require a diagnosis and then a prescription?

12 A. Yes.

13 Q. Could you explain?

14 A. In order to diagnose EIPH, you have to send a scope down  
15 into the horse's lungs after exercise to see if there's blood  
16 present, and how much. So all cases of EIPH are not equal.  
17 Some horses don't require treatment. The general philosophy is  
18 if it's mild they would not be necessarily treated. And it is,  
19 by some practitioners, considered normal to have a small amount  
20 of bleeding after extreme exercise.

21 So without that diagnostic test and the physical  
22 examination of the horse and the history of whether the horse's  
23 performance is stable or suffering, you kind of have to put all  
24 those pieces together to come up with a diagnosis of whether  
25 this horse needs to be treated for EIPH or not.

M1PPFIS4

Bowman - Direct

1 Q. Is this product, HP Bleeder Plus an FDA approved drug?

2 A. No.

3 Q. Were you asked to conduct a GRASE analysis of HP Bleeder  
4 Plus?

5 A. Yes.

6 Q. And what were your conclusions?

7 A. My conclusions are that there is no adequate,  
8 well-controlled studies out there to show that this product is  
9 effective or safe.

10 MS. MORTAZAVI: Your Honor, the government offers  
11 Government Exhibit 1000 to 1003, 1005 to 1011, and 1013 to 1053  
12 into evidence. These were subject to the same stipulation I  
13 mentioned earlier, Government Exhibit 9008. They are  
14 electronic extractions from files from a computer recovered  
15 from Seth Fishman's residence.

16 THE COURT: They're received into evidence.

17 (Government's Exhibits 1000 to 1003, 1005 to 1011, and  
18 1013 to 1053 received in evidence)

19 MS. MORTAZAVI: Ms. Jung, could you please pull up and  
20 publish to the jury Government Exhibit 1018, and could you  
21 please zoom in on the label.

22 BY MS. MORTAZAVI:

23 Q. Dr. Bowman, do you see here on your screen the label for HP  
24 Bleeder?

25 A. I do.

M1PPFIS4

Bowman - Direct

1 Q. Could you read the company name that appears on the  
2 left-hand side of the screen?

3 A. Specialized Performance Compounds.

4 Q. Is there a website associated with it?

5 A. On the label it lists a website address.

6 Q. And what is that?

7 A. WWW.SPC-brands.com.

8 Q. Could you please read the directions and ingredients that  
9 appear on this label?

10 A. The directions: Administer 5.0 cc IV or IM, six to eight  
11 hours before exercise. This product contains no known testable  
12 ingredients.

13 Ingredients: Proprietary blend of complex amino acid  
14 structures.

15 Q. Does this label contain all the information that the FDA  
16 typically requires on a drug label?

17 A. No.

18 Q. What, if any, information is missing?

19 A. There is a lot of missing information. There's no  
20 indications on the label; so there's no information on the use  
21 of the product beyond the implied use in the product name. The  
22 ingredient statement is inadequate for any parenteral drug,  
23 which is any kind of injectable drug. All the ingredients need  
24 to be listed, with the percentage of each ingredient in the  
25 formulation, and you can't claim that it's a proprietary blend.

M1PPFIS4

Bowman - Direct

1 You have to specifically provide the name of every ingredient.

2 There's no prescription legend. Because this is  
3 administered IV, there needs to be a prescription legend, which  
4 says: "Caution: Federal law restricts this drug to use by or  
5 on the order of a licensed veterinarian."

6 There needs to be full information on the manufacturer  
7 or the distributor, including contact information with a valid  
8 address and telephone number. And I'm probably forgetting a  
9 couple other things that are required to be on there, but I  
10 think that's it.

11 Q. You mentioned contact information, is that website that's  
12 listed at the bottom of this label sufficient to satisfy that  
13 requirement for the manufacturer?

14 A. No. The language is specifically spelled out in 21 CFR 200  
15 what it needs to be, and then it needs to say, you know,  
16 "distributed by" or "manufactured for" and then it lists the  
17 complete company name, address and phone number, and it can  
18 also have a website. It's not that a website isn't something,  
19 but it needs to have all of that information.

20 Q. So a website isn't a replacement for the other information  
21 that you described?

22 A. No.

23 MS. MORTAZAVI: Ms. Jung, could you please pull up,  
24 just for the parties, Government Exhibit 9012.

25 And, your Honor, this is another stipulation between

M1PPFIS4

Bowman - Direct

1 the parties I'd like to read into the record:

2 If called to testify at trial, law enforcement agents  
3 with the Federal Bureau of Investigation would testify that on  
4 March 9th, 2020, law enforcement agents with the Federal Bureau  
5 of Investigation conducted a search of the Golden Shoe Training  
6 Center, a racehorse training facility, at street address 261  
7 Bullville Road, Montgomery, New York, 12549. The Bullville  
8 property.

9 Government Exhibits 1400 through 1420, and 9500  
10 through 9505, are physical items, including paper records,  
11 seized from the Bullville property at the time of the search,  
12 or photographs fairly and accurately depicting the Bullville  
13 property, or photographs fairly and accurately depicting items  
14 during the search of the Bullville property.

15 On March 9th, 2020, law enforcement agents with the  
16 Federal Bureau of Investigation conducted a search of the Mount  
17 Hope Training Center, a racehorse training facility at street  
18 address, 335 Guymard Turnpike, Middletown, New York 10940. The  
19 Guymard property.

20 Government Exhibits 1500 through 1511 and 9600 through  
21 9604 are physical items, including paper records seized from  
22 the Guymard property at the time of the search, or photographs  
23 fairly and accurately depicting the Guymard property, or  
24 photographs fairly and accurately depicting items taken during  
25 the search of the Guymard property.

M1PPFIS4

Bowman - Direct

1           On March 9th, 2020, law enforcement agents with the  
2       Federal Bureau of Investigation conducted a search of the  
3       residence of Jorge Navarro at street address 10477 Southwest  
4       49th Place, Cooper City, Florida 33332. The 49th Place  
5       property.

6           Government Exhibits 1200 through 1222, and 9200  
7       through 9216, are physical items, including paper records,  
8       seized from the 49th Place property at the time of the search,  
9       or photographs fairly and accurately depicting the 49th Place  
10      property, or photographs fairly and accurately depicting items  
11      taken during the search of the 49th Place property.

12          On or about March 14th, 2019, law enforcement agents  
13      with the Federal Bureau of Investigation conducted a search of  
14      a horse barn used by Christopher Oakes at street address 121  
15      Bald Mountain Road, Bear Creek Village, Pennsylvania 18702.  
16      The Bald Mountain property.

17          Government Exhibits 1100 through 1128, and 9300  
18      through 9311, are physical items, including paper records,  
19      seized from the Bald Mountain property at the time of the  
20      search, or photographs fairly and accurately depicting the Bald  
21      Mountain property, or photographs fairly and accurately  
22      depicting items taken during the search of the Bald Mountain  
23      property.

24          It's further stipulated and agreed, by and between the  
25      parties, that the aforementioned government exhibits and this

M1PPFIS4

Bowman - Direct

1 stipulation, which is Government Exhibit 9012, may be received  
2 in evidence at trial.

3 So, your Honor, the government offers into evidence  
4 Government Exhibit -- the following Government Exhibits: 9012,  
5 1400 through 1420, 9500 through 9505, 1500 through 1511, 9600  
6 through 9604, 1200 through 1222, 9200 through 9216, 1100  
7 through 1128, and 9300 through 9311.

8 THE COURT: All of those exhibits are received in  
9 evidence.

10 (Government's Exhibits 9012, 1400 through 1420, 9500  
11 through 9505, 1500 through 1511, 9600 through 9604, 1200  
12 through 1222, 9200 through 9216, 1100 through 1128, and 9300  
13 through 9311 received in evidence)

14 MS. MORTAZAVI: Thank you.

15 Ms. Jung, with that, could you please pull up the  
16 following government exhibits for the parties and the jury:  
17 1122, 1123 and 1124, which are all items seized, as I indicated  
18 in the stipulation, on March 14th, 2019, of a horse barn owned  
19 by Christopher Oakes.

20 BY MS. MORTAZAVI:

21 Q. Dr. Bowen, could you please read out the name that appears  
22 in Government Exhibit 1122, to the extent you can read the  
23 label?

24 A. HP Bleeder Plus.

25 Q. All right. Do these exhibits all appear to be of the same

M1PPFIS4

Bowman - Direct

1 bottle from different angles?

2 A. Yes.

3 Q. If you could then read what appears on the labeling, under  
4 directions and ingredients?

5 A. Directions: Administer 10 cc's IV or IM five to eight --  
6 it's five to six, I misread it -- five to six hours --

7 THE COURT: Dr. Bowman?

8 A. -- before exercise. Ahh, that's better.

9 THE COURT: Yes. Thank you.

10 A. This product contains no known testable ingredients.

11 Q. And if you could read the ingredients on the label?

12 A. Ingredients: Proprietary blend of homeopathic and complex  
13 amino acid structures.

14 Q. Thank you.

15 Ms. Jung, could you please pull up Government  
16 Exhibit 1101, which is another item that was seized from the  
17 same search of Christopher Oakes' horse barn.

18 Could you read out, Dr. Bowman, the company name that  
19 appears on this label, to the extent you can identify one?

20 A. It has a logo and it says Specialized Performance  
21 Compounds.

22 Q. And is there a website associated with this company?

23 A. Yes, it's WWW.SPC-brands.com.

24 Q. Ms. Jung, could you please pull up Government Exhibits  
25 1407, 1408, 1409 and 1410, which are all items that were seized

M1PPFIS4

Bowman - Direct

1 during the search of the racehorse training facility called  
2 Golden Shoe.

3 And, Dr. Bowman, does this appear to be photos of the  
4 same bottle from different angles?

5 A. Yes.

6 Q. And again, to the extent you can -- and Ms. Jung may be  
7 able to assist us here -- could you please read the product  
8 name?

9 A. The product name is HP Bleeder Plus.

10 Q. And the ingredients?

11 A. The ingredients: Proprietary blend of homeopathic and  
12 complex amino acid structures.

13 Q. Thank you. And is there a company name that appears on  
14 this logo?

15 Ms. Jung, if you could go back to the original set of  
16 four exhibits.

17 A. Specialized Performance Compounds.

18 Q. Ms. Jung, we can take down this set of exhibits, and if you  
19 could please pull up Government Exhibits 1200, 1202 and 1203,  
20 which are all exhibits, and they are mentioned in the prior  
21 stipulation seized from a search of a premises associated with  
22 Jorge Navarro.

23 Dr. Bowman, once again, could you read the product  
24 name for this particular bottle?

25 A. Yes, this is HP Bleeder. I can't see a plus on this one,

M1PPFIS4

Bowman - Direct

1 homeopathic bleeder.

2 Q. And the ingredients?

3 A. Ingredients: Proprietary blend of complex amino acid  
4 structures.

5 Q. And there appears to be a website at the bottom of the  
6 label. Could you please read that out loud as well?

7 A. Yes, WWW.SPC-brands.com.

8 Q. Thank you.

9 Ms. Jung, we can take down this set of exhibits.

10 I'd like to direct the jurors to their binders, to the  
11 tab 125-AT, and I'll ask Ms. Jung to please pull up that  
12 particular exhibit, as well as Exhibit 125-A. I think there  
13 may be one or two jurors who are still trying to find their  
14 place so we'll wait another minute.

15 THE COURT: Yes, if you would all look up maybe once  
16 you're ready, okay?

17 MS. MORTAZAVI: Ms. Jung, if you could please --

18 THE COURT: No, no, no. Give it a minute.

19 MS. MORTAZAVI: Pardon me.

20 THE COURT: Anybody who needs more time? All right.

21 Thank you, Ms. Mortazavi.

22 MS. MORTAZAVI: Ms. Jung, could you please play  
23 Government Exhibit 125-A.

24 (Audio played)

25 And for the record, your Honor, that was a portion of

M1PPFIS4

Bowman - Direct

1 a call intercepted on April 3rd, 2019, between Seth Fishman and  
2 Jordan Fishman, as represented on Government Exhibit 125-AT.

3 Ms. Jung, could you please go back to Government  
4 Exhibit 711.

5 BY MS. MORTAZAVI:

6 Q. Dr. Bowman, do you see at the bottom, in red, under or  
7 beside the No. 2, "bleeding pills"?

8 A. Yes.

9 Q. Ms. Jung, could you please turn to the second page of this  
10 exhibit, and if you could enhance the writing that appears at  
11 the top of the page.

12 Dr. Bowman, could you please read out a portion of  
13 this description starting with the first paragraph?

14 A. Yes. "Bleeder pills increase vascular integrity and help  
15 reduce inflammation. They have coagulant properties as well.  
16 They have benefits far beyond bleeding. If you wanted to make  
17 an analogy, they would be equivalent to giving a low-dose  
18 corticosteroid for prevention of bleeding."

19 Q. Let me ask you about some of those terms. Vascular  
20 integrity, are you familiar with that?

21 A. Common sense interpretation is vascular --

22 MR. FERNICH: Objection.

23 THE COURT: Sustained.

24 Q. Are you familiar with the term "vascular"?

25 A. Yes.

M1PPFIS4

Bowman - Direct

1 Q. What does that mean?

2 A. So vascular has to do with the veins and arteries,  
3 circulatory system.

4 Q. And the term "coagulant" that appears in that second  
5 sentence, are you familiar with that word?

6 A. Yes.

7 Q. What does "coagulant" mean?

8 A. A coagulant property is a property that would make the  
9 blood clot better, faster.

10 Q. All right. And if you could read the first sentence of the  
11 second paragraph that follows?

12 A. "HP Bleeder Plus is a strong natural vasodilator and mild  
13 natural analgesic."

14 Q. Are there any claims made here about the drug's intended  
15 use?

16 A. Yes.

17 Q. What are those?

18 A. So it claims that this drug will be a vasodilator, which is  
19 a classic drug and an analgesic, another class of drugs; so it  
20 will perform those functions.

21 Q. Is that similar to the HP Bleeder Plus product that you  
22 testified about earlier?

23 A. Those are some of the same intended uses.

24 Q. And these bleeder pills, are these FDA approved?

25 A. No.

M1PPFIS4

Bowman - Direct

1 Q. Were you asked to conduct a GRASE analysis on this  
2 particular product?

3 A. Yes.

4 Q. What did you conclude?

5 A. I couldn't find any published information that provided any  
6 data to support that these pills are safe or effective.

7 MS. MORTAZAVI: Ms. Jung, could you please pull up for  
8 the parties and the jury Government Exhibit 1125, which again  
9 is --

10 THE COURT: Ms. Mortazavi, if you're going to a new  
11 exhibit, this might be a good time for a break.

12 MS. MORTAZAVI: Certainly, your Honor.

13 THE COURT: Is this convenient for you, or am I  
14 breaking you mid-stream?

15 MS. MORTAZAVI: This is a fine point. We're happy to  
16 pick up here after the lunch break.

17 THE COURT: All right. Ladies and gentlemen, we'll  
18 take the lunch break now. If you can please be ready to be  
19 back in your seats for us to resume no later than 2:00 p.m.  
20 All right?

21 (Jury not present)

22 THE COURT: All right. Dr. Bowman, you remain under  
23 oath, and you should not discuss your testimony with anyone  
24 over the break, please. All right?

25 Everyone, have a good lunch, and I'll see you back

M1PPFIS4

Bowman - Direct

1 here a little bit before 2:00.

2 MR. FERNICH: Judge, could I -- it's extrinsic to  
3 this. Could I raise something that's come up separate from  
4 this?

5 THE COURT: Yes, hold on.

6 Dr. Bowman, you can have lunch, and we'll see you back  
7 here. If you can try to be here ten to 2:00, five to 2:00.

8 THE WITNESS: All right.

9 THE COURT: All right. If we could let Dr. Bowman  
10 excuse herself and everyone have a seat for a moment.

11 (Witness temporarily excused)

12 THE COURT: Okay.

13 MR. FERNICH: Judge, as it happens, I handled the  
14 appeal for El Chappo. In an unfortunate bit of timing, the  
15 Second Circuit denied the appeal as we started this morning, in  
16 a published opinion, and I've gotten, you know, quite a few  
17 press requests for comment, and I've given a, you know,  
18 one-sentence comment.

19 Obviously, it's not intended to affect the jury in  
20 this case. I'm not a party to the litigation. I don't know  
21 that any action needs to be taken. I'm not suggesting that it  
22 does. I'm just alerting you that this happened, and I'm sad  
23 that it happened at this time, but, obviously, it's beyond my  
24 control.

25 THE COURT: All right. I appreciate the advice.

M1PPFIS4

Bowman - Direct

1 Anything from the government?

2 MR. ADAMS: Nothing, your Honor.

3 THE COURT: All right. Thank you.

4 Have a good lunch, everyone. See you back here a bit  
5 before 2:00.

6 (Luncheon recess)

7 (Continued on next page)

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M1PTFIS5

Bowman - Direct

## AFTERNOON SESSION

(2:00 p.m.)

THE COURT: The jury is on its way up.

I just want to say one thing for the record. When we were at the sidebar, Mr. Fernich -- I think it was you -- cited a case to me, *Garcia*, you also said "Scope." I don't know if that was the name of the case or you were talking about the scope of an examination. But in any event, if you're going to be using names like *Garcia* that appears in thousands of case names, you need to give me a better orientation going forward, please.

MR. FERNICH: I understand. I spelled S-C-O-P out for the reporter, which is 846 F.2d. And actually I think I misspoke about *Garcia*, I think it's called -- your Honor's point is taken, I think it's called *Cruz*, I think it's 981.

THE COURT: *Cruz*, you're saying?

MR. FERNICH: I think *Cruz*.

THE COURT: Not much better.

MR. FERNICH: They say the same thing. Your Honor could grasp my point.

THE COURT: Okay, thank you. As I say, the jury is on its way up, so we'll be ready to resume.

Mr. Adams and Ms. Mortazavi, when we conclude for the day, I will ask you to give us an update of how we're doing in terms of anticipated scheduling. Okay?

M1PTFIS5

Bowman - Direct

1 MR. ADAMS: Certainly. Thank you.

2 THE COURT: Thank you.

3 (Jury present)

4 THE COURT: Dr. Bowman, you remain under oath.

5 Ms. Mortazavi, please.

6 MS. MORTAZAVI: Thank you.

7 Ms. Jung, please pull up for government and the  
8 parties Government Exhibit 1125.

9 BY MS. MORTAZAVI:

10 Q. Dr. Bowman, if you recall before the lunch break we were  
11 discussing what was labeled Bleeder Pills on Government  
12 Exhibit 711. I would like to direct your attention to this  
13 exhibit. It's a photograph of an item that was observed during  
14 a search on March 14, 2019, of a horse barn associated with  
15 Christopher Oakes.

16 Apart from the brown pills that appear in that Ziploc  
17 bag, do you see two other items enmeshed in those brown pills?

18 A. Yes.

19 Q. Are you able to read the label on those items?

20 THE COURT: Can we zoom in?

21 A. Maybe if you zoom in.

22 Q. If the answer is no, that's perfectly acceptable.

23 A. I could read some of it, I can't read the label.

24 THE COURT: Sorry, you need to speak into the mic.

25 A. I can't read the name.

M1PTFIS5

Bowman - Direct

1 Q. All right. Thank you, Dr. Bowman.

2 MS. MORTAZAVI: Ms. Jung, we can take this exhibit  
3 down.

4 Your Honor, I would like to read into the record a  
5 stipulation between the parties that was just signed this  
6 morning. It's Government Exhibit 9006.

7 If called as a witness at trial, a record custodian  
8 for the entity Equestology, Inc., Equestology, and for each of  
9 the government exhibits identified below would testify that  
10 Government Exhibits 300 through 320E and 320FA through 331 are  
11 true and correct copies of certain records of Equestology  
12 maintained by Equestology and are records of regularly-  
13 conducted activities of Equestology that remained at or near  
14 the time by or from information transmitted by someone with  
15 knowledge of the information contained therein, kept in the  
16 course of regularly-conducted activities of Equestology, and  
17 made in the regular practice of the activities of Equestology.

18 It is further stipulated and agreed by and between the  
19 parties that the aforementioned government exhibits and this is  
20 stipulation, which is Government Exhibit 9006, may be received  
21 in evidence at trial.

22 Your Honor, the government offers Government  
23 Exhibit 9006 and the exhibits referenced therein, 300 through  
24 320E and 320FA through 331 into evidence.

25 THE COURT: Those are all received as evidence.

M1PTFIS5

Bowman - Direct

1 (Government's Exhibits 9006, 300 through 320E and  
2 320FA through 331 received in evidence)

3 MS. MORTAZAVI: Ms. Jung, please pull up for the  
4 parties and the jury Government Exhibit 306.

5 Could you please zoom in on the text at the top,  
6 Ms. Jung.

7 BY MS. MORTAZAVI:

8 Q. Dr. Bowman, does this appear to be an email?

9 A. Yes, it does.

10 Q. I would like us to read portions of this exhibit into the  
11 record.

12 Looking at the bottom there's an email from Lisa  
13 Ranger. In the from section, could you read the email address  
14 associated with Lisa Ranger?

15 A. Yes, it's equestology@gmail.com.

16 Q. What was the date at which this email was sent?

17 A. March 18, 2017.

18 Q. And who is the recipient on this chain email?

19 A. Seth Fishman.

20 Q. Could you read out the email address associated with Seth  
21 Fishman, please.

22 A. Yeah, sethfishman@hotmail.com.

23 Q. And the subject of this email?

24 A. Can you please give a short explanation of the bleeding  
25 pills, how they differ from Homeopathic Bleeder Plus, why use

M1PTFIS5

Bowman - Direct

1 together or by themselves.

2 Q. And the subject line of this the email is Bleeder Pills, is  
3 that right?

4 A. Correct.

5 Q. Now looking at the top email on this exhibit, could you  
6 tell us who sent the top email and when it was sent?

7 A. Dr. Fishman sent this email on March 18, 2017.

8 Q. And could you read out the recipients, please.

9 A. Lisa Ranger.

10 Q. Could you please then read the text in the body of the  
11 email?

12 A. Bleeder pills increase vascular integrity and help reduce  
13 inflammation. They have coagulant properties as well. They  
14 have benefits far beyond bleeding. If you wanted to make an  
15 analogy, they would be equivalent to giving a low dose  
16 corticosteroid for the prevention of bleeding. HP Bleeder Plus  
17 is a strong natural vasodilator and mild natural analgesic.  
18 Vasodilators are extremely beneficial for many reasons beyond  
19 decreasing bleeding in horses. The natural analgesic is just  
20 an added benefit as pain will increase likelihood of bleeding.

21 MS. MORTAZAVI: Ms. Jung, you can take this exhibit  
22 down.

23 Please pull up Government Exhibit 711 and turn to page  
24 2.

25 Q. Dr. Bowman, again this is the document that we were

M1PTFIS5

Bowman - Direct

1 referencing earlier in your testimony this morning. Looking  
2 next to the No. 3 and the product that is listed beside it,  
3 could you read out the name of the product?

4 A. VO2 Max.

5 Q. And there's a highlighted portion to this text. Please  
6 read that out as well.

7 A. HP Bleeder plus with additional ingredients. Usually 10  
8 mls usually four to five fors prior to race.

9 Q. And is fors spelled F-O-R-S?

10 A. Yes.

11 Q. Please read the first two sentences that appear in the  
12 description below the portion that you just read.

13 A. All natural Japanese amino acid-based product that has  
14 profound vasodilatory properties. Vasodilation benefits all  
15 performance animals because it reduces cardiac exertion during  
16 performance.

17 Q. Dr. Bowman, just for sake of clarity, what does cardiac  
18 refer to?

19 A. Cardiac refers to the work that the heart is doing in this  
20 case.

21 Q. All right.

22 A. Cardiac exertion.

23 Q. Could you read the next sentence starting with  
24 pharmaceutical vasodilators.

25 A. Pharmaceutical vasodilators are usually tested in most

M1PTFIS5

Bowman - Direct

1 jurisdictions and disciplines because they are proven to be  
2 effective sports enhancing. Vasodilation significantly reduces  
3 EIPH, Exercise-Induced Pulmonary Hemorrhage, and lactic acid  
4 accumulation. The formula is a proven oral prework designed  
5 for Olympic athletes.

6 Q. Dr. Bowman, I will stop you there. Exercise-Induced  
7 Pulmonary Hemorrhage or EIPH, just to remind us all, was that  
8 the same condition that was described with respect to  
9 Homeopathic Bleeder Plus?

10 A. Yes.

11 Q. And at a high level, does that consist of bleeding in a  
12 horse's lungs?

13 A. Yes.

14 Q. Could you read the last two sentences in this description  
15 of the VO2 Max, starting with dose is 10ten to 20.

16 A. Dose is 10 to 20 mls intravenously for a 1,000 pound or  
17 450-kilogram. Although this product will not interfere with  
18 other medications, do not mix with anything else in the same  
19 syringe.

20 Q. Looking at the description, Dr. Bowman, are there any  
21 claims made about intended uses for this product?

22 A. In the previous paragraph it made claims that it was a  
23 vasodilator and analgesic and it would reduce cardiac work and  
24 reduce lactic acid. And the directions for use about when to  
25 use it imply that the expected use --

M1PTFIS5

Bowman - Direct

1 MR. FERNICH: Objection.

2 THE COURT: Sustained.

3 Q. All right. Dr. Bowman, looking at the description, is this  
4 the type of drug that would require a diagnosis before it's  
5 administered?

6 A. Yes.

7 Q. Is VO2 Max FDA approved?

8 A. No.

9 Q. Were you asked to conduct a GRASE analysis of VO2 Max?

10 A. Yes.

11 Q. What were your conclusions?

12 A. I was unable to locate any adequate well-controlled studies  
13 that support the use of this product or any of these uses,  
14 vasodilation or to reduce lactic acid accumulation or to reduce  
15 cardiac exertion.

16 MS. MORTAZAVI: Ms. Jung, could you please pull up  
17 Government Exhibit 1028.

18 And Ms. Jung, are you able to zoom in on part of the  
19 label?

20 THE COURT: Do you have the ability to rotate it?

21 MS. MORTAZAVI: We may not, your Honor, we may have to  
22 do it manually.

23 Q. Dr. Bowman, I apologize for that.

24 A. It's okay.

25 Q. Could you read out the product name that appears here?

M1PTFIS5

Bowman - Direct

1 A. VO2 Max.

2 Q. And the directions and then the ingredients?

3 A. Directions: Administer intravenously 10 to 20 CCs one to  
4 four hours prior to strenuous exercise.

5 Q. And the ingredients?

6 A. Ingredients: Proprietary blend of amino acids.

7 Q. Does this label contain all the information the FDA  
8 typically requires on an approved drug label?

9 A. No.

10 Q. What is missing?

11 A. There's no indication section to describe when you should  
12 use the product. It lacks the --

13 MR. FERNICH: Objection.

14 THE COURT: Grounds?

15 MR. FERNICH: It's inconsistent with the face of the  
16 document.

17 THE COURT: You can cross-examine.

18 MR. FERNICH: Thank you, your Honor.

19 THE COURT: Sorry, Dr. Bowman, go ahead, you can  
20 answer.

21 A. It lacks that federal law restricts this drug to use by a  
22 licensed veterinarian, the prescription legend. It lacks who  
23 it's manufactured by or distributed by, that information. I  
24 don't see a batch number or lot number or an expiration date.  
25 It lacks an adequate ingredient statement. It should have all

M1PTFIS5

Bowman - Direct

1 the ingredients listed, including the inactive ingredients  
2 specifically, not just "proprietary blend."

3 Q. Dr. Bowman, you stated there was no expiration date. I  
4 know this label is a little difficult to read. I want to make  
5 sure to clarify. The words in red text at the bottom --

6 A. Yes, EXP, I missed it.

7 Q. But otherwise, looking at the label, do you see any  
8 manufacturer information?

9 A. No.

10 Q. Do you see a name or address associated with a manufacturer  
11 or distributor?

12 A. No.

13 MS. MORTAZAVI: Ms. Jung, please pull up Government  
14 Exhibits 1114, 1115, 1116 and 1117. And these are items that  
15 were observed during a search of the horse barn associated with  
16 Christopher Oakes on March 14, 2019.

17 Could we please, Ms. Jung, zoom in on Government  
18 Exhibit 1117.

19 Q. Dr. Bowman, please read the name of this product.

20 A. This is VO2 Max.

21 Q. To the extent you can, I know it's a little difficult, if  
22 you could read the text that appears in red underneath the name  
23 of the product.

24 A. Administer intravenously 10 CCs, I think it says four to  
25 six hours prior to strenuous exercise. Proprietary blend of

M1PTFIS5

Bowman - Direct

1 amino acids.

2 MS. MORTAZAVI: Thank you. You can take down these  
3 exhibits.

4 I would like to direct the jurors to their transcript  
5 binders, Government Exhibit 127BT. I will have Ms. Jung pull  
6 up that exhibit and Government Exhibit 127B.

7 This refers to a portion of a call that's intercepted  
8 on April 4, 2019, between Seth Fishman and Nick Devita.

9 THE COURT: So I'm clear on this, when you say 127BT,  
10 T is what is in the transcript binder and 127B is the actual  
11 recording?

12 MS. MORTAZAVI: That's correct, your Honor.

13 THE COURT: Thank you.

14 MS. MORTAZAVI: I believe all the jurors have the  
15 transcript open, so I ask Ms. Jung to please play Government  
16 Exhibit 127B.

17 (Audio recording played)

18 MS. MORTAZAVI: If you could please pull up Government  
19 Exhibit 711, and please turn to page 2.

20 Q. Dr. Bowman, next to No. 4 there appears the name homeogesic  
21 and then in parenthesis natural analgesic pain killer.

22 Can you remind us what an analgesic is?

23 A. An analgesic is a pain reliever.

24 Q. Could you please read this first paragraph that appears  
25 under that caption.

M1PTFIS5

Bowman - Direct

1 A. Three products in one. A combination of the three most  
2 common preparatory products in global racing combined in one  
3 product for the most value and benefit. MSM and DMG are well  
4 documented in racing industry and are both included in the  
5 highest bioavailable concentration. Proprietary analgesic  
6 combinations based on a published peer reviewed article are  
7 included as the third product.

8 Q. And could you read the last sentence that appears in this  
9 description. I believe it's in the following paragraph  
10 starting with the literature -- sorry, the second to last  
11 sentence appearing in the next paragraph starting with the  
12 literature regarding.

13 A. The literature regarding the benefits or both MSM and DMG  
14 in the equine athlete is endless. Now both are available in a  
15 combination therapy with the added benefit of a proven  
16 analgesic.

17 Q. Dr. Bowman, when you're conducting your GRASE analysis do  
18 you look to each individual component or ingredient in a drug?

19 A. Not for evidence of the well-controlled studies on that  
20 product.

21 Q. Do you look to the drug as a whole?

22 A. We look to the drug as a whole, and it needs to actually be  
23 the formulation that is in use. So it can't be someone else's  
24 formulation, especially if we don't know all the ingredients,  
25 because we can't confirm that it would be identical to this

M1PTFIS5

Bowman - Direct

1 product.

2 Q. Is it sufficient if each individual ingredient is generally  
3 recognized as safe and effective?

4 A. No.

5 Q. Why not?

6 A. Because, just as I said, it's the finished product that is  
7 being tested. You can have the same ingredients in three  
8 different products and they might all have different  
9 half-lives, which mean they last in the body for different  
10 lengths of time until half of it's gone, it's a common  
11 pharmacokinetic measurement, or they might reach different  
12 highest C max, which is the highest concentration that you get  
13 in the blood, and that is important, it matters to the safety  
14 and effectiveness.

15 Q. So does the interaction of all the ingredients matter when  
16 you're reviewing safety and efficacy?

17 A. Always, yes.

18 MS. MORTAZAVI: Ms. Jung, please go back to the  
19 original exhibit, page 2 of Government Exhibit 711, and turn to  
20 the next product, No. 5, PSDS natural analgesic pain killer.

21 Q. Could you had please read the portion in bold, Dr. Bowman,  
22 that appears underneath the name of this drug.

23 A. This product is based on the original Panacin formulation.  
24 It has 2.5 times more D-Phenylalanine than all other compounded  
25 and production versions.

M1PTFIS5

Bowman - Direct

1 Q. Dr. Bowman, are you familiar with Panacin?

2 A. I wasn't, but I went and did some research.

3 Q. What did you find?

4 A. I found --

5 MR. FERNICH: Objection.

6 THE COURT: Lay a better foundation, please.

7 Q. What did you review, Dr. Bowman, when looking into Panacin?

8 A. I reviewed information found in Daily Med and some of the  
9 other medical websites. There are two formulations of Panacin,  
10 there's one for --

11 MR. FERNICH: Objection.

12 THE COURT: What's the objection?

13 MR. FERNICH: My objection is it violates the  
14 confrontation clause under *Williams v. Illinois*.

15 THE COURT: Overruled.

16 A. So there's a human drug called Panacin that's a tablet, at  
17 least I only saw it in a tablet form. It's sold in Europe.  
18 It's not sold in the United States. It's not approved here.  
19 It includes acetaminophen, which is the active ingredient in  
20 Tylenol, caffeine and aspirin. And then there was reference to  
21 a veterinary formulation, so I searched further and I found  
22 that --

23 MR. FERNICH: Objection.

24 THE COURT: Same objection?

25 MR. FERNICH: It exceeds the bounds of her expert

M1PTFIS5

Bowman - Direct

1 testimony. She's quoting research she did in this particular  
2 case.

3 THE COURT: Lay a better foundation.

4 Q. Dr. Bowman, you mentioned that you had come across various  
5 versions of Panacin, correct?

6 A. Correct.

7 Q. And you testified about a human version, is that right?

8 A. Yes.

9 Q. And you mentioned that you looked into Daily Med, I  
10 believe, in order to do your research?

11 A. That's one place I checked, yes.

12 Q. And is that a database or a publication or something else?

13 A. It's a database, NIH maintains it, it's publicly available,  
14 and all the approved drugs are found.

15 Q. And the research that you did, was that in connection with  
16 your testimony today?

17 A. Yes.

18 Q. In the course of your research, did you come to learn about  
19 a different version of Panacin that's intended for animal use?

20 A. Yes.

21 Q. Could you tell us what you know about Panacin with respect  
22 to animal use?

23 A. It has two amino acids. It's reported to have two amino  
24 acids.

25 MR. FERNICH: Objection.

M1PTFIS5

Bowman - Direct

1 THE COURT: Sustained.

2 Q. Dr. Bowman, I turn back to PSDS on Government Exhibit 711.  
3 Could you please read the first sentence underneath the portion  
4 that you just read starting with: It is a mild.

5 A. It is a mild antiinflammatory compound and is a prominent  
6 component in wound healing. Carnosine is a major muscle  
7 buffer. In muscle tissue, phosphate and carnosine together  
8 provide approximately 90 percent of the buffering capacity.

9 Q. Dr. Bowman, I will pause you there.

10 MS. MORTAZAVI: Could you please turn to -- and this  
11 is directed to Ms. Jung, if you could please turn to the next  
12 page in this exhibit, which is page 3.

13 Q. Dr. Bowman, do you see that the PSDS description continues  
14 on the next page?

15 A. Yes.

16 Q. Could you please read the sentence starting with: With  
17 increasing acidity?

18 A. With increasing acidity comes premature muscle fatigue with  
19 an associated decrease in performance.

20 Q. Let me pause you there. Looking at the last few sentences  
21 in bold in this description, could you please read that portion  
22 out loud, starting with: Best used over.

23 A. Best used over two to three days prior to strenuous  
24 exercise. The typical dose is five mls and the last dose is  
25 usually administered four to six hours prior to strenuous

M1PTFIS5

Bowman - Direct

1 exercise. Given its safety, many trainers opt to give 10 mls  
2 for the last dosage.

3 Q. Dr. Bowman, looking at the entirety of that explanation of  
4 PSDS, are there any claims made about the intended use of PSDS?

5 A. It's making a claim to improve performance throughout its  
6 buffering capacity and as an antioxidant, and it reduces muscle  
7 fatigue and improves muscle function.

8 Q. Is PSDS FDA approved?

9 A. No, it's not.

10 Q. Were you asked to conduct a GRASE analysis of PSDS?

11 A. Yes.

12 Q. What were your conclusions?

13 A. My conclusions are that it's an unapproved new animal drug.  
14 There's no adequate and well-controlled studies regarding its  
15 use.

16 MS. MORTAZAVI: Ms. Jung, please pull up for the  
17 parties and the jury Government Exhibit 1027.

18 Q. Dr. Bowman, could you read the name of this product.

19 A. Pain Shot LC.

20 Q. And again, you may have to crane your neck, but could you  
21 read out the description -- or apologies, the directions that  
22 appear on this label.

23 A. Directions: Administer 10 to 15 mls IM or IV slowly 24  
24 hours something four to six hours prior to strenuous exercise.

25 Q. All right. It says --

M1PTFIS5

Bowman - Direct

1 A. 24 hours and four to six hours prior.

2 Q. Okay. And on this particular government exhibit, 1027,  
3 which was an extraction from a computer that was found in Seth  
4 Fishman's residence, could you please tell us if this label  
5 contains all the information the FDA typically requires on an  
6 approved drug label?

7 A. No, it does not.

8 Q. What, if any, information is missing?

9 A. There's no indication section. The prescription legend is  
10 it absent. Although it says keep refrigerated, that is not  
11 usually adequate for the storage instructions.

12 MR. FERNICH: The what?

13 Q. Dr. Bowman, if you could repeat what you just said.

14 A. Although it says keep refrigerated, that doesn't usually  
15 suffice for the storage instructions which are required on the  
16 label for all OTC and prescription drugs. I may have forgotten  
17 to mention that earlier. There are so many things on the label  
18 that need to be there.

19 Q. Dr. Bowman, again, this could be me because of where I'm  
20 located in the courtroom, if you could pull the microphone  
21 close to your mouth. And I think you should feel free to move  
22 the microphone if you need to.

23 THE COURT: She just did.

24 MS. MORTAZAVI: Thank you, your Honor.

25 Ms. Jung, if we could take down this exhibit and

M1PTFIS5

Bowman - Direct

1 return to Government Exhibit 711. If you turn to page 3.

2 Q. Next to No. 7 appearing on this page, Dr. Bowman, GNRH,  
3 could you please read the description starting with Gondorelin  
4 Acetate?

5 A. Gondorelin Acetate is similar to Factrel and identical in  
6 sequence to Cystorelin. This product is best used for sulking  
7 horses. Typically one-half to full bottle is used four to six  
8 hours prior to strenuous exercise. Both Factrel and Cystorelin  
9 require refrigeration, and if not stored properly they may lose  
10 potency. As a lyophilized presentation, GNRH is less likely to  
11 degrade and lose potency if not stored under refrigeration at  
12 all times.

13 Q. That first phrase, Dr. Bowman, which I won't attempt to  
14 pronounce again, are you familiar with that term?

15 A. Gondorelin Acetate?

16 Q. Yes.

17 A. Yes, that's the active ingredient in several approved new  
18 animal drugs.

19 Q. When you say the active ingredient, is that the same as an  
20 API?

21 A. Yes.

22 Q. Looking at Factrel, which is also included in this  
23 description, are you familiar with that term?

24 A. Yes.

25 Q. What is it?

M1PTFIS5

Bowman - Direct

1 A. That's an approved new animal drug.

2 Q. And Cystorelin also appears in that sentence. Are you  
3 familiar with that term?

4 A. Yes.

5 Q. What is that?

6 A. That is also an approved new animal drug.

7 Q. Can you remind us, Dr. Bowman, can someone else manufacture  
8 an approved new animal drug once it's been approved?

9 A. No, not unless they go through the approval process and get  
10 their own approval.

11 Q. In the second sentence, Dr. Bowman, there's a reference to  
12 sulking horses. Are you familiar with a sulking horse?

13 A. A sulking horse would be the same as a sour horse.

14 Typically those are horses that are reluctant to leave their  
15 stall or leave the barn area. They don't like to go out and  
16 work.

17 Q. Is this product, GNRH, FDA approved?

18 A. This product isn't, but there are FDA approved GMRHs.

19 Q. When you say this product isn't, what do you mean by that?

20 A. I mean as far as the labels that I saw were not for the FDA  
21 approved product, they were for an unapproved new animal drug  
22 with the same active ingredient.

23 Q. Again, when you check for new animal drugs that are  
24 approved by the FDA, does it matter who the manufacturer is?

25 A. Yes.

M1PTFIS5

Bowman - Direct

1 Q. Were you asked to conduct a GRASE analysis on GNRH?

2 A. Yes.

3 Q. What were your conclusions?

4 A. My conclusions were that there are no adequate well-  
5 controlled studies to support the use of this drug and it's an  
6 unapproved new animal drug.

7 MS. MORTAZAVI: Ms. Jung, please pull up Government  
8 Exhibit 1023, which is an electronic extraction from a computer  
9 found at Seth Fishman's residence.

10 Q. Dr. Bowman, could you he read the name of the product  
11 appearing on this label.

12 A. GNRH, Gondorelin Diacetate.

13 Q. And the directions?

14 A. Directions. Reconstitute with 20 mls bacteriostatic water.  
15 Each ml contains 50 micrograms GNRH. Use IM or IV for as  
16 prescribed by veterinarian.

17 Q. Just looking at the label, is this the type of drug that  
18 would require a diagnosis and a prescription?

19 A. Yes.

20 Q. Does this label contain all of the information that the FDA  
21 would typically require on a new drug label?

22 A. No.

23 Q. What's missing?

24 A. It misses the indications section, the manufacturer and  
25 distributor information and contact information. It is lacking

M1PTFIS5

Bowman - Direct

1 a full ingredient -- well, it may not be. Without knowing  
2 more, I don't know if it's listing all the ingredients. It  
3 lacks the storage statement for the product before  
4 reconstitution. And did I say the prescription legend is  
5 missing?

6 Q. Is there a manufacturer listed here?

7 A. No.

8 Q. Any manufacturer address?

9 A. No.

10 MS. MORTAZAVI: Ms. Jung, could you please pull up  
11 Government Exhibit 1417, 1418, 1419 and 1420, these are all  
12 admitted, and photographs of items that were observed during  
13 the search of the Golden Shoe training facility.

14 Q. Dr. Bowman, can you see these appear to be photographs of a  
15 label from different angles of the same drug?

16 A. Yes.

17 Q. Can you read the drug name?

18 A. The drug name is GNRH, Gonadorelin Diacetate.

19 Q. And to the extent you could read the directions, could you  
20 please read those out loud?

21 A. Directions: Reconstitute with 20 mls bacteriostatic water.  
22 Each ml contains 50 micrograms GMRH. Use IM or IV as  
23 prescribed by veterinarian.

24 MS. MORTAZAVI: Ms. Jung, please zoom in on Government  
25 Exhibit 1420 in the bottom right corner.

M1PTFIS5

Bowman - Direct

1 Q. Do you see a company name on this label?

2 A. It says Specialized Performance Compounds.

3 Q. Was that present in our review of the last exhibit,  
4 Government Exhibit 1023?

5 A. No, it wasn't.

6 MS. MORTAZAVI: And Ms. Jung, could you please pull up  
7 Government Exhibit 1507. This is a photograph of an item that  
8 was observed during the premises search of the Mount Hope  
9 training facility.

10 If you could zoom in on the label, Ms. Jung.

11 Q. Dr. Bowman, again, could you read out the name of this  
12 product?

13 A. This is GMRH, Gonadorelin Diacetate.

14 Q. And I won't have you read out the directions, but do they  
15 appear to be identical to the label that you reviewed  
16 previously?

17 A. Yes.

18 MS. MORTAZAVI: Ms. Jung, please pull up Government  
19 Exhibit 711, and turn to page 3 of that exhibit.

20 Q. Dr. Bowman, looking at the bottom, looking next to No. 8,  
21 do you see the name ITTP Plus?

22 A. Yes.

23 Q. What's in parenthesis next to that product name?

24 A. Increase oxygen release in the blood.

25 Q. Could you read the description that follows?

M1PTFIS5

Bowman - Direct

1 A. ITPP plus other ingredients. ITPP increases oxygen  
2 release. Compared to what's sold online, its lets than one  
3 half the price. Most people are using one half bottle night  
4 before and remainder of bottle four to five hours before event.

5 MS. MORTAZAVI: And Ms. Jung, if we could please pull  
6 up Government Exhibit 1025, and zoom in on one of those labels.

7 Q. Could you read the product name here, Dr. Bowman.

8 A. This is IT Plus.

9 Q. And the directions.

10 A. Directions: Reconstitute with 30 mls bacteriostatic water  
11 and administer 15 mls 24 hours and four hours before exercise.

12 Q. Dr. Bowman, were you asked to check FDA's databases to see  
13 if IT Plus is FDA approved?

14 A. Yes.

15 Q. Is it FDA approved?

16 A. No, it isn't.

17 Q. Were you also asked to conduct a GRASE analysis of IT Plus?

18 A. Yes.

19 Q. What were your conclusions?

20 A. My conclusions were that it's an unapproved new animal  
21 drug. There aren't adequate and well-controlled studies to  
22 support its use.

23 Q. Looking at the label, does this label contain all the  
24 information that the FDA typically requires?

25 A. No.

M1PTFIS5

Bowman - Direct

1 Q. What is missing?

2 A. There's no indication section. The prescription legend is  
3 missing. There's no storage information. It lacks an  
4 ingredients section that is complete. It's inadequate to say  
5 proprietary amino acids and sugars, you have to list each one  
6 with its concentration in the final formulation.

7 Q. Is there a manufacturer listed here?

8 A. No, it's lacking the manufacturer distributor information.

9 MS. MORTAZAVI: I would like to direct the jurors to  
10 pick up their transcript binders once again and have Ms. Jung  
11 pull up Government Exhibit 132AT.

12 And I will have Ms. Jung prepare Government Exhibit  
13 132A.

14 And while the jurors are locating the transcript, for  
15 record, this is a portion of an intercepted call taking place  
16 on April 17, 2019 between Seth Fishman and Richard Silverman.

17 It appears all the jurors have found the transcript,  
18 so Ms. Jung, if you could please play Government Exhibit 132A.

19 (Audio recording played)

20 MS. MORTAZAVI: Thank you, Ms. Jung. Please pull up  
21 Government Exhibits 1118, 1119, 1120 and 1121, which are all  
22 photographs of items that were observed during the March 14,  
23 2019 search of Christopher Oakes' horse barn.

24 Q. Dr. Bowman, again with respect to the two exhibits to the  
25 right, 1120 and 1121, does that appear to be the same bottle

M1PTFIS5

Bowman - Direct

1 but from different angles?

2 A. Yes.

3 MR. ADAMS: Ms. Jung, if could you zoom in on 1120 and  
4 1121.

5 Q. Could you read the product name, Dr. Bowman, that appears  
6 on this label.

7 A. This one is ITTP plus.

8 Q. And if you could read the beginnings of the directions,  
9 whatever is legible under Government Exhibit 1120.

10 A. Directions: Reconstitute bacteriostatic water and  
11 administer IV 24 hours and four hours before -- I can't read  
12 that word.

13 Q. And Dr. Bowman, are you familiar with that term,  
14 "reconstitute?"

15 A. Yes.

16 Q. What does that mean?

17 A. There are a lot of medications that come in lyophilized  
18 form, so they're powder in a vial. You take that powder and  
19 you reconstitute it with the liquid that's specified, whether  
20 that's sterile water or, in this case, bacteriostatic water.

21 Q. So does reconstitute mean to combine or mix?

22 A. Combine or mix. And it turns the powder in a liquid. You  
23 shouldn't still see flakes or crystals in that after you add  
24 the liquid.

25 Q. And what's bacteriostatic water?

M1PTFIS5

Bowman - Direct

1 A. It's a diluent, something that you mix with drugs. It has  
2 a little bit of alcohol in it, and the remainder, I believe, is  
3 just sterile water. There is an approved -- I don't know if  
4 this has been approved, but there is an FDA-approved  
5 bacteriostatic water.

6 MS. MORTAZAVI: Ms. Jung, you can take down these  
7 exhibits, and please pull up Government Exhibit 143C and 143C2.  
8 And I will ask the jurors to open up their binders to 143CT.

9 While they're doing so, I will say for the record this  
10 is a portion of a call intercepted on June 12, 2019, between  
11 Seth Fishman, John Pundyk and Geoff Vernon.

12 And Ms. Jung, if you could please play Government  
13 Exhibit 143C.

14 (Audio recording played)

15 MS. MORTAZAVI: Ms. Jung, if you could take down this  
16 exhibit and return to Government Exhibit 711. And turn to page  
17 4 of that exhibit.

18 Q. Dr. Bowman, looking at No. 9 at the top of the page, do you  
19 see product named TB-7?

20 A. Yes.

21 Q. Can you read what is in parentheses beside TB-7?

22 A. Accelerated tissue repair, especially in lungs.

23 Q. Could you read the first few sentences starting with: This  
24 product has.

25 A. This product has the same sequencing as the infamous TB500

M1PTFIS5

Bowman - Direct

1 product, except now available at a fraction of the cost. TB500  
2 marketed this well-studied sequence from the many published  
3 results in the numerous use patents filed for this sequence.

4 Q. I will pause you there, Dr. Bowman. Looking at the first  
5 paragraph, can you locate the last sentence -- sorry, the next  
6 to last sentence starting with "Like all immunomodulators," and  
7 please read beginning with that portion.

8 A. Like all immunomodulators, they are highly beneficial in  
9 small strategic doses and promote overall healing and increased  
10 immunity. Helps in after-race care for bleeders. Proactively  
11 promotes healing.

12 Q. Dr. Bowman, are there any claims made here about the  
13 intended uses of TB-7?

14 A. Yes.

15 Q. What are those?

16 A. Its intended uses, to improve and speed, apparently,  
17 healing of the lungs following bleeding after a race. It  
18 increases -- it says it's an immunomodulator. That means it's  
19 going to increase the immunity. That should be something that  
20 helps prevent infections.

21 Q. Anything else, Dr. Bowman?

22 A. That's all I see.

23 Q. Is this product TB-7 FDA approved?

24 A. No, it's not.

25 Q. Were you asked to conduct a GRASE analysis of TB-7?

M1PTFIS5

Bowman - Direct

1 A. Yes.

2 Q. What were your conclusions?

3 A. That TB-7 is an unapproved new animal drugs.

4 Q. Are there any well-controlled studies in the literature  
5 regarding TB-7?

6 A. No.

7 MS. MORTAZAVI: Ms. Jung, please pull up Government  
8 Exhibit 1024. If you could zoom in on one of these portions of  
9 the label.

10 This is an electronic extraction from a computer found  
11 in Seth Fishman's residence.

12 Q. Could you read the product name here, Dr. Bowman?

13 A. TB-7 Acetylated Thymosin Beta 4 and 10.

14 Q. Do you see a company named here?

15 A. Equestology.

16 Q. Is there any contact information associated with that  
17 company?

18 A. No.

19 Q. Do you see the phrase in red at the bottom: For R and D  
20 and clinical trial use only, exclamation mark?

21 A. Yes.

22 Q. Are you familiar with the term R and D?

23 A. That typically means research and development.

24 Q. Can you explain what that is?

25 A. That's not a terminology that is used on an FDA label, but

M1PTFIS5

Bowman - Direct

1 research and development is the research that is done behind  
2 new products, whether new drugs or other things.

3 Q. And do you see here the reference to clinical trial?

4 A. Yes.

5 Q. You testified before about clinical trials and how that  
6 data can be used to inform the drug approval process, correct?

7 A. Correct.

8 Q. Are there certain drugs that are permitted to be used for  
9 clinical trial purposes?

10 A. Yes.

11 Q. Does the FDA track those drugs?

12 A. Yes.

13 Q. Can you explain?

14 A. When companies come in and they're interested in pursuing a  
15 new animal drug, the first step is setting up an  
16 investigational new animal drug file, and in that file is where  
17 all the early data is collected. Every drug that is  
18 distributed for use in a clinical trial has a special statement  
19 on the label, it's found at 21 CFR 511. If it's for use in a  
20 clinical trial, it says for investigational use only, and for  
21 clinical trials in horses, for use in clinical trials only.  
22 That might not be the exact language but it's pretty close. So  
23 this statement would have no regulatory meaning.

24 Q. So in other words, the statement that is recognized for  
25 drugs that can be used in a clinical trial, does that statement

M1PTFIS5

Bowman - Direct

1 appear on this label?

2 A. No.

3 Q. Looking at the label as a whole, excluding the section in  
4 red, is there any information here that is missing that the FDA  
5 would typically require?

6 A. The labels we require for investigational drugs are  
7 different, so it doesn't meet that standard. And it certainly  
8 doesn't meet the standard as we described of an approved new  
9 animal drug label. It doesn't have an indication section. It  
10 doesn't have storage information. It doesn't have the  
11 manufactured by and distributed by information with the contact  
12 information. It doesn't include the dose or the directions for  
13 administration. It doesn't have any cautions or precautions or  
14 warnings to let you know what might go wrong, what you should  
15 be looking for for adverse events or how to select the proper  
16 patients for it.

17 MS. MORTAZAVI: Ms. Jung, please take down this  
18 exhibit and pull up Government Exhibits 1111, 1112 and 1113,  
19 which are all items that were observed during the March 14,  
20 2019 search of the horse barn associated Christopher Oakes.

21 If we could, please, focus on Government Exhibit 1112,  
22 Ms. Jung.

23 Q. Dr. Bowman, can you read the name that appears on this  
24 label.

25 A. This is TB-7, Acetylated Thymosin Beta 4 and Beta 10.

M1PTFIS5

Bowman - Direct

1 Q. Looking at this collection of exhibits, do there appear to  
2 be on this label any reference to the company or the  
3 manufacturer of this particular drug?

4 A. No, all I see is a faint logo.

5 Q. And is that logo an image or does it include any writing?

6 A. I just see an image.

7 (Continued on next page)

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M1PPFIS6

Bowman - Direct

1 Q. And again, what information, if you could give one or two  
2 examples, is missing from this label that the FDA would  
3 otherwise require?

4 A. It lacks an indication section. It lacks a complete -- I'm  
5 assuming. I don't see an ingredient panel; so it doesn't have  
6 the proper ingredient statement. It lacks the prescription  
7 legend. It lacks indications, warnings, precautions.

8 Q. And Doctor --

9 A. And storage information.

10 Q. Dr. Bowman, with reference to the last exhibit we looked  
11 at, which was the TB-7 label, Government Exhibit 1024, the  
12 language for "R and D and clinical trial use only" appeared in  
13 red. Do you see that phrase on any of these images?

14 A. No, I don't.

15 Q. Ms. Jung, could you please take down these exhibits and  
16 pull up Government Exhibits 1216, 1217, 1218 and 1219.

17 These are all objects that were seized during the  
18 search of Jorge Navarro's residence.

19 Dr. Bowman, could you read the product name out once  
20 again?

21 A. TB-7, Acetylated thymosin B4 and B10.

22 Q. Is there a manufacturer or distributor listed here?

23 A. No.

24 Q. Do you see the phrase "for R and D clinical trial use only"  
25 listed here?

M1PPFIS6

Bowman - Direct

1 A. No.

2 Q. Ms. Jung, you can take these exhibits down, and if you  
3 could please turn back to Government Exhibit 711, page 4.

4 Dr. Bowman, looking at the bottom of the page, next to  
5 No. 13, do you see the product name ACTH?

6 A. Yes.

7 Q. Could you read what appears after ACTH?

8 A. "In small doses will act as natural anti-inflammatory.  
9 Larger doses, two cc's or more, will act as sedation."

10 Q. And could you read the next two sentences that follow?

11 A. "With testing of corticosteroids, there are not many viable  
12 options left. ACTH, adrenocorticotrophic hormone, causes the  
13 adrenal gland to release cortisol, the body's natural  
14 corticosteroid. Most companies supply this peptide in an  
15 aqueous base formulation with questionable stability."

16 Q. And I'll stop you there.

17 Ms. Jung, could we turn to the next page, that's page  
18 5.

19 Dr. Bowman, could you read the description that starts  
20 on page 5 starting with the sentence "each vial contains a  
21 thousand"?

22 A. "Each vial contains 1,000 international units and is  
23 reconstituted and kept in refrigerator for longest shelf life.  
24 The bottle, once reconstituted, should be used within five  
25 days."

M1PPFIS6

Bowman - Direct

1 Q. Looking at this description of ACTH, are there any claims  
2 made about its intended use?

3 A. Yes.

4 Q. What are some of those?

5 A. It claims that it will cause the release of natural  
6 corticosteroids in the body for an anti-inflammatory effect.

7 Q. And is this drug, ACTH, FDA approved?

8 A. This ACTH isn't FDA approved, but there are approved ACTHs.

9 Q. And what's the difference between this ACTH and the  
10 approved versions?

11 A. This one is a little more concentrated, I believe. I would  
12 have to --

13 Q. And Dr. Bowman --

14 A. -- refresh my memory.

15 Q. I'll rephrase the question, for the sake of clarity.

16 The FDA approved versions of ACTH, are they  
17 manufactured by any of the company names that you were provided  
18 by the prosecution?

19 A. No.

20 Q. And so this version of ACTH, were you checking the approval  
21 against the potential manufacturers that you were provided by  
22 the prosecution?

23 A. Yes.

24 Q. Were you also asked to conduct a GRASE analysis of ACTH?

25 A. Yes.

M1PPFIS6

Bowman - Direct

1 Q. And what were your conclusions?

2 A. My conclusions were that this version of ACTH is an  
3 unapproved new animal drug, and there aren't any adequate or  
4 well-controlled studies to support its use.

5 Q. Ms. Jung, could you please take down this exhibit and pull  
6 up Government Exhibit 1022, which again is an electronic record  
7 from a computer found at Seth Fishman's residence.

8 Dr. Bowen, could you read the product name?

9 A. ACTH.

10 Q. And under the directions, if you could read those as well?

11 A. "Reconstitute with 5 mls bacteriostatic water. Administer  
12 2.5 to 5 mls IM or IV or as prescribed by veterinarian."

13 Q. Would this be the type of product that would require a  
14 prescription before it's dispensed?

15 A. Yes.

16 Q. Why is that?

17 A. Because you need a diagnosis to use it properly. The two  
18 common uses for ACTH, the approved uses, one is as a diagnostic  
19 test to diagnose Cushing's disease in horses; so you use ACTH  
20 to stimulate the natural release of corticosteroids. You do a  
21 pre-injection blood sample, post-injection blood sample, have  
22 both those blood samples tested to see if the horse can respond  
23 to the administration of the ACTH, and that provides your  
24 diagnosis of, yes, it's Cushing's; no, it's not. If it can  
25 respond it's not a Cushing's horse.

M1PPFIS6

Bowman - Direct

1           The other use, which is a very old use on the old  
2 labels is in animals with a deficiency of ACTH, which in modern  
3 veterinary times we realize there really weren't any  
4 deficiencies. It's not something that's deficient.

5 Q. And looking at this label, Dr. Bowman, does there appear to  
6 be a manufacturer name?

7 A. No.

8 Q. Does there appear to be any sort of address or telephone  
9 number associated with the manufacturer?

10 A. No.

11 Q. And what about contact information for a distributor?

12 A. No.

13 Q. Are there any ingredients here?

14 A. No, just the concentration of the one active.

15 Q. All right. Ms. Jung, if you could take down this exhibit,  
16 and please pull up Government Exhibits 1400, 1401, 1402 and  
17 1403, which were all items that were found during a premises  
18 search of the Golden Shoe Training Center.

19           Dr. Bowman, could you read the product name that  
20 appears on this label?

21 A. This is ACTH, the thousand international unit vial  
22 injection size.

23 Q. All right. And again, does this set of exhibits appear to  
24 be the same bottle, just from different angles?

25 A. Yes.

M1PPFIS6

Bowman - Direct

1 Q. Looking at these various exhibits, is there a manufacturer  
2 or distributor name?

3 A. No.

4 Q. And, Dr. Bowman, is there any ingredients listed in these  
5 labels?

6 A. Only the concentration of the active ingredient.

7 Q. Ms. Jung, if you could take these exhibits down, and please  
8 pull up Government Exhibits 1508, 1509, 1510 and 1511, which  
9 are all items that were observed during the search of the Mount  
10 Hope Training Center.

11 And, Dr. Bowman, once again, do these exhibits appear  
12 to depict the same bottle, from different angles?

13 A. Yes.

14 Q. Could you read the product name?

15 A. ACTH.

16 Q. All right. And looking at these exhibits, do you see a  
17 manufacturer or distributor name?

18 A. No, I don't.

19 Q. Contact information for a manufacturer or distributor?

20 A. No.

21 Q. And if Ms. Jung could zoom in on Government Exhibit 1510  
22 and 1511.

23 Dr. Bowman, do you see any ingredients listed?

24 A. No, only the concentration of the one active ingredient.

25 Q. Thank you.

M1PPFIS6

Bowman - Direct

1 And, Ms. Jung, you can take down these exhibits.  
2 Ms. Jung, if you could please return to Government Exhibit 711.  
3 Turn to page 7 of that exhibit.

4 Next to No. 19, Dr. Bowman, do you see the word  
5 "Serenity" and in parenthesis "sedation"?

6 A. Yes.

7 Q. Could you please read out the three sentences that follow?

8 A. "It's an antianxiety, for the most part. Takes away stress  
9 without affecting performance. Typically 5 to 10 cc's, IV,  
10 four to six hours before event."

11 Q. Looking towards the bottom of this description, Dr. Bowman,  
12 do you see the sentence starting with "It was also shown"?

13 A. Yes.

14 Q. Could you start reading from that sentence up to the end of  
15 this description?

16 A. "It was also shown to increase GABA and stimulates Dopamine  
17 in the brain. More recent studies have shown it can increase  
18 serotonin levels as well. Having the ability to increase three  
19 key neurotransmitters, the end result is a distressed mind and  
20 muscle relaxation."

21 Q. Any claims here made about Serenity's intended use?

22 A. Yes.

23 Q. Can you describe some of those?

24 A. They're describing it as an antianxiety medication, without  
25 effecting performance; so that's like something that trainers

M1PPFIS6

Bowman - Direct

1 love because the horses get very anxious before competition.

2 MR. FERNICH: Objection, move to strike.

3 THE COURT: Sustained, but I'm not striking.

4 A. Okay.

5 Q. Dr. Bowman, let me ask you specifically about sedation. Is  
6 the claim to sedate an animal a claim that would affect the  
7 structure or function of the animal?

8 A. Yes.

9 Q. All right. And there are references here to a few  
10 different chemicals. Are you familiar with Dopamine?

11 A. Yes.

12 Q. What is that?

13 A. It's a brain neurotransmitter that is responsible for  
14 calmness. It's a calming, happy neurotransmitter.

15 Q. In looking at this description, would this be the type of  
16 drug that requires a prescription?

17 A. Yes.

18 Q. And why do you say that?

19 A. First of all, because it's given IV. By that route of  
20 administration alone, it requires the skill of a veterinarian  
21 or a veterinarian to determine that a particular client would  
22 have the skill to administer it. In which case, they could  
23 dispense it or give them a prescription for it.

24 Q. Is Serenity FDA approved?

25 A. No, it isn't.

M1PPFIS6

Bowman - Direct

1 Q. Were you asked to conduct a GRASE analysis of Serenity?

2 A. Yes.

3 Q. What were your conclusions?

4 A. My conclusions are there are no adequate, well-controlled  
5 studies to support its use, and it's a non-approved new animal  
6 drug.

7 Q. Thank you.

8 And, Ms. Jung, could you please pull up Government  
9 Exhibit 319-S, which is a record of Equestology Inc.

10 Dr. Bowman, looking at this label, is there any  
11 manufacturer information?

12 A. No, there isn't.

13 Q. Any distributor information?

14 A. No.

15 Q. Is there any company name that appears on this label?

16 A. No.

17 Q. And for the sake of the record, what's the name of this  
18 product?

19 A. This is Serenity.

20 Q. Could you please read out the ingredients listed for this  
21 product?

22 A. Proprietary sugars and amino acid blend.

23 Q. What information, if any, is missing from this label that  
24 the FDA would typically require?

25 A. There would be required to be an indication section,

M1PPFIS6

Bowman - Direct

1 telling you when to use it and whether there's any  
2 contraindications to use. There would have to be a complete  
3 ingredient statement, where each ingredient was listed along  
4 with its concentration. There needs to be any cautions or  
5 precautions about the use of the drug, or information on any  
6 adverse events that might occur because of it so people know  
7 what to look out for. It needs to be in the prescription legend.

8 Q. Thank you. Dr. Bowman -- I'm sorry.

9 Ms. Jung, if we could please take down this exhibit.

10 And, Dr. Bowman, I'd like to review one or two e-mails  
11 with you.

12 THE COURT: Before we do that, Ms. Mortazavi, is this  
13 a convenient point for a break?

14 MS. MORTAZAVI: It is, your Honor.

15 THE COURT: All right. Ladies and gentlemen, we'll  
16 take our afternoon break now. If we can keep it to 15 minutes  
17 maximum, which means you're ready to come back up in about ten  
18 minutes. Okay? We'll try to get you out on time today. Okay?  
19 Thank you.

20 (Jury not present)

21 THE COURT: All right. I'll see everyone back here  
22 slightly before 3:20, please.

23 And, Dr. Bowman, you remain under oath.

24 THE WITNESS: Thank you.

25 (Recess)

M1PPFIS6

Bowman - Direct

1 THE COURT: Please be seated. The jurors are on their  
2 way.

3 MS. MORTAZAVI: Your Honor, with respect to timing,  
4 there's a chance I'll be able to conclude my direct  
5 examination, not by 4:30 but potentially by 5:00. Given the  
6 late start, would the Court like me to proceed past 4:30?

7 THE COURT: Let's see if the jurors are willing to  
8 stick it out. Okay?

9 MS. MORTAZAVI: Certainly.

10 THE COURT: Is that your preference, Mr. Sercarz, that  
11 we press on and try to finish the direct?

12 MR. SERCARZ: Yes, as long as we can get done by 5:00.

13 THE COURT: Okay. Let's see where we're at, and  
14 Ms. Mortazavi, if you just kind of keep me informed as best you  
15 can.

16 MS. MORTAZAVI: Yes, I will do my best, your Honor.

17 MR. SERCARZ: It may please the Court to know that in  
18 the aftermath of the events of yesterday, the government and  
19 defense counsel are speaking about trying to streamline the  
20 case, to some degree.

21 THE COURT: Okay. That's always a good thing, anyway.  
22 I think in terms of the jurors will appreciate it.

23 MR. FERNICH: I'm sure you will too.

24 THE COURT: Well, I will, that's true, but the jurors  
25 are more important than I am at this point, at least for all of

M1PPFIS6

Bowman - Direct

1 you.

2 Now, tomorrow morning you all have to be tested again,  
3 right?

4 MS. MORTAZAVI: Yes, your Honor.

5 MR. SERCARZ: That's right, your Honor.

6 THE COURT: Is that going to be arranged before hours  
7 so we can start at our normal time, or are we going to be a  
8 little delayed?

9 MR. ADAMS: Before hours. The court's website said  
10 they'll be available I think as early as 7:00 a.m.

11 THE COURT: All right.

12 MS. MORTAZAVI: And, your Honor, the courtroom staff  
13 had given us boxes of the test to self-administer, and we're  
14 able to text the results either to courthouse staff or to your  
15 Honor's chambers, whatever you prefer.

16 THE COURT: Well, you should do it -- why don't we do  
17 this, and I did ask my clerk to say this to you, Mr. Fernich,  
18 over the weekend, like when you're communicating with Covid  
19 response at SDNY, if you copy my chambers' e-mail, we'll be in  
20 the loop. I think that's what makes the most sense.

21 MS. MORTAZAVI: We'll plan to do that. Thank you,  
22 your Honor.

23 THE COURT: Thank you.

24 (Jury present)

25 THE COURT: Please be seated, everyone.

M1PPFIS6

Bowman - Direct

1 Dr. Bowman, you remain under oath.

2 And, Ms. Mortazavi, please.

3 MS. MORTAZAVI: Thank you.

4 BY MS. MORTAZAVI:

5 Q. Dr. Bowman, before the afternoon break, we were discussing  
6 a product called Serenity; do you recall that?

7 A. Yes.

8 Q. And I was about to review a set of e-mails with you that  
9 I'm going to have Ms. Jung pull up now.

10 Ms. Jung, if you could pull up Government Exhibit 308,  
11 which is a record of Equestology, and if you could zoom in on  
12 the text portion. Thank you.

13 Dr. Bowman, do you see at the bottom there is a  
14 lower-in-chain e-mail dated June 8th, 2017, from Lisa Ranger?

15 A. Yes.

16 Q. Can you read the body of that e-mail?

17 A. "Can you write a short explanation about Serenity and how  
18 to use it?"

19 Q. And at the top e-mail, do you see that there's another  
20 June 8th, 2017, e-mail from Seth Fishman to Lisa Ranger?

21 A. Yes.

22 Q. Could you read the subject line?

23 A. Regarding: Serenity/Equility.

24 Q. And then the body of that e-mail?

25 A. "I can make a simple description, if you want. It's an

M1PPFIS6

Bowman - Direct

1 antianxiety, for the most part. Takes away stress without  
2 affecting performance. Typically 5 to 10 cc's, IV, four to six  
3 hours before the event."

4 Q. Thank you.

5 Ms. Jung, if you could pull up Government Exhibit 304,  
6 which is also a record of Equestology.

7 And looking at the top portion of this e-mail,  
8 Dr. Bowman, do you see that this is sent from Lisa Ranger to  
9 Seth Fishman?

10 A. Yes.

11 Q. Could you read the subject of this e-mail?

12 A. "Serenity," "Regarding: Serenity."

13 Q. And the date it was sent?

14 A. June 22nd, 2017.

15 Q. And do you see the lower-in-chain e-mail below that dated  
16 June 21st, 2017, from Seth Fishman?

17 A. Yes.

18 Q. All right. I'd like you to read a portion of this,  
19 starting with, if you go a few lines down, "L-theanine can  
20 cross the blood," if you can read that portion of this e-mail,  
21 please?

22 A. Yes. "L-theanine can cross the blood-brain barrier and has  
23 many published studies demonstrating it can significantly  
24 reduce anxiety and stress. It was also shown to increase GABA  
25 and stimulates dopamine in the brain. More recent studies have

M1PPFIS6

Bowman - Direct

1 shown it can increase serotonin as well. Having the ability  
2 to increase three key neurotransmitters. The end result is a  
3 distressed mind and muscle relaxation."

4 Q. I'll pause you there. You testified earlier that dopamine  
5 is a neurotransmitter; is that right?

6 A. Yes.

7 Q. And in the prior exhibit there was a reference to cc's.  
8 Can you tell us what cc's are, if you know?

9 A. Cc's are the same as milliliters. It's two big  
10 centimeters.

11 Q. Is it just a measure of volume?

12 A. Exactly. And they're equivalent, one cc equals one ml.

13 Q. And then below the portion that you read, could you read  
14 out the sentence starting with "Interesting to note"?

15 A. "Interesting to note that the IOC and WADA were thinking to  
16 ban the amino acid because of the profound effect it had on  
17 certain events."

18 Q. And the line that follows, please?

19 A. "I would suggest using this in most horses because there is  
20 really no downside and does seem to work very well in human  
21 athletes."

22 Q. Ms. Jung, if you could take down this exhibit.

23 And, Dr. Bowman, were you asked to do a GRASE analysis  
24 of a product described as BB3?

25 A. Yes.

M1PPFIS6

Bowman - Direct

1 Q. Were you also asked to check whether BB3 is FDA approved?

2 A. Yes.

3 Q. Is it FDA approved?

4 A. No, it is not.

5 Q. And what were the results of your GRASE analysis of BB3?

6 A. A BB3 is an unapproved new animal drug, and there were no  
7 well-controlled studies -- adequate and well-controlled studies  
8 to support its use.

9 Q. Ms. Jung, could you please pull up Government Exhibit 1220,  
10 which is an item that was seized during a premises search of  
11 the residence of Jorge Navarro.

12 And, Dr. Bowman, could you read the label here?

13 A. BB3.

14 Q. Any ingredients listed here?

15 A. No.

16 Q. Any manufacturer information?

17 A. No.

18 Q. Other than the words BB3, for the record, anything  
19 appearing on this label?

20 A. No.

21 Q. Ms. Jung, if you could please take down this exhibit, and  
22 I'm going to direct the jurors back to their transcript  
23 binders, to Government Exhibit 113-AT.

24 And I'll ask Ms. Jung to please pull up that exhibit  
25 and the recording, Government Exhibit 113-A, which for the

M1PPFIS6

Bowman - Direct

1 record is a portion of an intercepted call dated February 21st,  
2 2019, between Seth Fishman and Jeff Gillis.

3 I believe we're waiting on one or two jurors who are  
4 still trying to locate the tab. We'll give them a minute.

5 JUROR: Tab?

6 THE COURT: 113-A, like, Apple, T, for transcript.

7 (Pause)

8 MS. MORTAZAVI: All right. Ms. Jung, if you could  
9 please play Government Exhibit 113-A.

10 (Audio played)

11 And, Ms. Jung, if you could please pull up Government  
12 Exhibit 113-BT, and I'm going to direct the jurors to the next  
13 tab in their binder, which is 113-BT, as well, and I'll have  
14 Ms. Jung prepare Government Exhibit 113-BT.

15 Again, this is another portion of this same recorded  
16 call that we listened to earlier between Seth Fishman and Jeff  
17 Gillis.

18 Ms. Jung, if you could please play Government  
19 Exhibit 113-BT.

20 (Audio played)

21 Thank you, Ms. Jung.

22 BY MS. MORTAZAVI:

23 Q. Dr. Bowman, we earlier talked about erythropoietin being an  
24 API; do you recall testifying about that?

25 A. Yes.

M1PPFIS6

Bowman - Direct

1 Q. Do you know of any other terms or names used to referred to  
2 erythropoietin?

3 A. It's generally referred to as EPO as an abbreviation, and I  
4 think there are some other terms that are used, Epogen. Those  
5 are the ones I am familiar with.

6 Q. All right. So you're familiar with EPO and Epogen as  
7 referred to the API erythropoietin?

8 A. Yes.

9 Q. I'd like to direct the jurors to Government Exhibit 134-AT,  
10 which is also in their binders.

11 And I'll have Ms. Jung pull up Government  
12 Exhibit 134-AT and Government Exhibit 134-A. And for the  
13 record, that's a portion of an intercepted call dated May 5th,  
14 2019, between Seth Fishman and Richard Silverman.

15 And it looks as though all of the jurors have all  
16 their place in the binders; so I'll have Government  
17 Exhibit 134-A.

18 THE COURT: Are you able to zoom in on the screen,  
19 make it larger, so that anybody who prefers, can follow along  
20 that way? Thank you.

21 (Audio played)

22 MS. MORTAZAVI: Ms. Jung, if you could please take  
23 down these exhibits.

24 And the jurors can put away their binders for the time  
25 being.

M1PPFIS6

Bowman - Direct

1 And, Ms. Jung, if you could please pull up Government  
2 Exhibit 309, and zoom in on the text, please. Thank you.

3 BY MS. MORTAZAVI:

4 Q. Dr. Bowman, do you see at the top of this government  
5 exhibit an e-mail from Seth Fishman to Lisa Ranger dated  
6 January 5th, 2019?

7 A. Yes.

8 Q. And below that, do you see a lower-in-chain e-mail from  
9 Lisa Ranger to Seth Fishman on January 4th, 2019?

10 A. Yes.

11 Q. All right. Looking at the top e-mail dated January 5th,  
12 2019, can you read the three words that are in the body of that  
13 e-mail?

14 A. "Please see below."

15 Q. And then looking at the lower-in-chain e-mail, can you read  
16 the language in bold, starting with "Let's try this."

17 A. "Let's try this. Simple terms. Please input. For pain,  
18 tie up, attitude, inflammation, et cetera. I know you gave  
19 description, but I need a one-word blip to catch their  
20 attention. Without me suggesting or telling them. That way,  
21 they will question, then ask you or me about it."

22 Q. And looking at that list, Dr. Bowman, that has a list of  
23 names in red. Looking at GNRH, can you read the language in  
24 the black text that follows?

25 A. "Factrel, androgenic hormone."

M1PPFIS6

Bowman - Direct

1 Q. And was Factrel the product that you testified about  
2 previously when we were discussing GNRH?

3 A. Yes. Factrel is one of the FDA approved forms of GNRH for  
4 animals.

5 Q. Looking at the next line, ITTP Plus, can you read the black  
6 text that follows?

7 A. "Increased oxygen release in the blood."

8 Q. And can you read the line after that?

9 A. "Accelerated tissue repair, especially lung tissue."

10 Q. Does that language appear beside the product named TB-7?

11 A. Yes.

12 Q. Going a few lines down to EGH in red, can you please read  
13 the black text that follows?

14 A. "Increases testosterone."

15 Q. And again, a few lines down in red, PSDS. Can you read the  
16 black text that follows?

17 A. "Natural analgesic, painkiller."

18 Q. And below that in red, BB3. Can you please read the black  
19 text that follows?

20 A. "Long acting blood builder. Would only let trusted clients  
21 have this."

22 Q. Thank you.

23 Miss Jung, could you please take down this exhibit,  
24 and pull up Government Exhibits 4016 and 4017. Oh, and,  
25 Ms. Jung, if you could please take down that exhibit.

M1PPFIS6

Bowman - Direct

1 MS. MORTAZAVI: Your Honor, could I please read an  
2 additional stipulation into the record, which was signed by the  
3 parties? This is Government Exhibit 9015.

4 THE COURT: Yes.

5 MS. MORTAZAVI: If called to testify at trial, law  
6 enforcement agents with the Federal Bureau of Investigation or  
7 the Food and Drug Administration would testify that on or about  
8 October 28th, 2018, law enforcement agents with the Federal  
9 Bureau of Investigation conducted a search of the office and  
10 warehouse space associated with Equestology, Inc. -- the  
11 Equestology warehouse -- at street address 3500 Northwest 2nd  
12 Avenue, Unit No. 723, Boca Raton, Florida 33431.

13 Government Exhibits 9020 through 9086 are physical  
14 items seized from the Equestology warehouse property at the  
15 time of the search. On or about October 28th, 2019, law  
16 enforcement agents with the Federal Bureau of Investigation  
17 conducted a search of the residence of Seth Fishman, located at  
18 street address 2565 South Ocean Boulevard, No. 412N, as in  
19 Nancy, Boca Raton, Florida 33487. The Fishman residence.

20 Government Exhibits 6000 through 6005 are photographs  
21 fairly and accurately depicting the Fishman residence, or  
22 photographs fairly and accurately depicting the items taken  
23 during the search of the Fishman residence.

24 On or about October 28th, 2019, law enforcement agents  
25 with the Federal Bureau of Investigation conducted a search of

M1PPFIS6

Bowman - Direct

1 a storage unit associated with Equestology, Inc. -- the  
2 Equestology storage unit -- located at street address 189  
3 Linton Boulevard, Unit No. 757, Delray Beach, Florida 33444.

4 Government Exhibits 1300 through 1317 -- that's  
5 1317 -- are photographs fairly and accurately depicting the  
6 Equestology storage unit, or photographs fairly and accurately  
7 depicting items taken during the search of the Equestology  
8 storage unit.

9 On March 9th, 2020, law enforcement agents with the  
10 Federal Bureau of Investigation conducted a search of the  
11 residence of Lisa Giannelli at street address 125 Jennifer  
12 Lane, Felton, Delaware, 19943. The Giannelli residence.

13 Government Exhibits 5000 through 5018, and 9100  
14 through 9122 are: One, physical items, including paper  
15 records, seized from the Giannelli residence at the time of the  
16 search; or, two, photographs fairly and accurately depicting  
17 the Giannelli residence; or, three, photographs fairly and  
18 accurately depicting items taken during the search of the  
19 Giannelli residence.

20 On March 9th, 2020, law enforcement agents with the  
21 Federal Bureau of Investigation conducted a search of a horse  
22 barn used by Christopher Oakes at street address 121 Bald  
23 Mountain Road, Bear Creek Village, Pennsylvania 18702. The  
24 Bald Mountain property.

25 Government Exhibits 1800 through 1806, and 9400

M1PPFIS6

Bowman - Direct

1 through 9414 -- that's one-four -- are: One, physical items,  
2 including paper records, seized from the Bald Mountain property  
3 at the time of the search; or two, photographs fairly and  
4 accurately depicting the Bald Mountain property; or three,  
5 photographs fairly and accurately depicting items taken during  
6 the search of the Bald Mountain property.

7 Your Honor, the government moves for admission of this  
8 stipulation, which is Government Exhibit 9015, and the exhibits  
9 that are referenced therein, which I can read into the record  
10 again.

11 THE COURT: You don't need to read them into the  
12 record again, but did the end of that stipulation stipulate to  
13 the admissibility?

14 MS. MORTAZAVI: Yes, your Honor. I'll read that  
15 portion as well.

16 It is further stipulated and agreed by and between the  
17 parties that the aforementioned government exhibits in this  
18 stipulation, which is Government Exhibit 9015, may be received  
19 in evidence at trial.

20 THE COURT: Stipulation and all of the referenced  
21 exhibits are received and are evidence in this case.

22 (Government's Exhibits 9015, 9020-9086, 6000-6005,  
23 1300-1317, 5000-5018, 9100-9122, 1800-1806, 9400-9414 received  
24 in evidence)

25 MS. MORTAZAVI: Thank you, your Honor.

M1PPFIS6

Bowman - Direct

1 And, Ms. Jung, if we could pull up Government Exhibits  
2 4016 and 4017. These are both items that were photographed  
3 during the search of the Equestology office space.

4 BY MS. MORTAZAVI:

5 Q. Dr. Bowman, looking at this label -- and if we could have  
6 Ms. Jung please pull up the images; thank you, Ms. Jung -- do  
7 you see a company name or a manufacturer name on this label?

8 A. I see a logo with a company name Equi-Science.

9 Q. Do you see a product name?

10 A. Yes, EGH, equine growth hormone.

11 Q. And what are the directions for use?

12 A. Directions: Dose for 500 kilogram horse. 5 mls IM two  
13 times per week for eight weeks.

14 Q. Dr. Bowman, is EGH, as depicted here, FDA approved?

15 A. No.

16 Q. Were you asked to conduct a GRASE analysis of EGH?

17 A. No.

18 Q. All right. Does this label contain all of the information  
19 the FDA typically requires on an approved drug label?

20 A. No, it doesn't.

21 Q. Could you give us two examples of information that's  
22 missing?

23 A. Well, there's no indication section. There's no contact  
24 information on the manufacturer by or distributed by, and  
25 there's no complete ingredient list.

M1PPFIS6

Bowman - Direct

1 Q. Thank you.

2 Ms. Jung, could you please pull up what's been marked  
3 as Government Exhibits 1207, 1208, 1209 and 1210. These are  
4 all items that were found during a search of the residence  
5 associated with Jorge Navarro.

6 Dr. Bowman, once again, does this appear to be images  
7 of the same bottle from different angles?

8 A. Yes.

9 Q. Could you read the name that appears to be the product name  
10 for this bottle?

11 A. BPB.

12 Q. And, Ms. Jung, if you could focus on Government  
13 Exhibit 1209 and pull up the bottle image, and if you could do  
14 the same with Government Exhibit 1208.

15 Dr. Bowman, looking at this label, again, does there  
16 appear to be any manufacturer information?

17 A. No.

18 Q. Does there appear to be any contact information for a  
19 distributor?

20 A. No.

21 Q. Does there appear to be any ingredients listed here?

22 A. No.

23 Q. Ms. Jung, if you could take down these images, and please  
24 pull up Government Exhibit 1411, Government Exhibit 1412 and  
25 Government Exhibit 1413.

M1PPFIS6

Bowman - Direct

1           These are all items that were found during the search  
2 of the Golden Shoe Training Center.

3           And, Ms. Jung, if you could pull up the images on the  
4 left-hand side of 1411 and 1412. Thank you.

5           Dr. Bowman, can you again read the product name that  
6 appears on this bottle?

7 A. BPB.

8 Q. Once again, does there appear to be a manufacturer listed  
9 here?

10 A. No.

11 Q. What about ingredients?

12 A. No.

13 Q. Is this product, BPB, FDA approved?

14 A. No.

15 Q. Were you asked to do a GRASE analysis of BPB?

16 A. I honestly can't recall.

17 Q. Do you recall, Dr. Bowman, preparing a report in connection  
18 with your testimony here today?

19 A. Yes. I just don't recall if this drug was part of that  
20 report.

21 Q. All right. Would that report have listed information about  
22 the drugs that you did conduct a GRASE analysis on?

23 A. Yes.

24 Q. Would that report refresh your recollection?

25 A. Yes.

M1PPFIS6

Bowman - Direct

1 MS. MORTAZAVI: Your Honor, may I please pass up a  
2 copy of Dr. Bowman's report?

3 THE COURT: Yes.

4 MS. MORTAZAVI: And, your Honor, if I could approach  
5 the witness?

6 THE COURT: Sure.

7 MS. MORTAZAVI: Thank you.

8 THE COURT: Thank you.

9 (Pause)

10 THE WITNESS: Thank you. So yes, BPB was on the list  
11 of drugs I examined.

12 MR. SERCARZ: Your Honor, can I please find out if it  
13 refreshed her recollection?

14 THE COURT: Dr. Bowman, I'm going to instruct you  
15 please don't read the report.

16 THE WITNESS: Okay.

17 THE COURT: Let Ms. Mortazavi ask you questions  
18 specifically. She gave it to you for the purpose of refreshing  
19 your recollection.

20 THE WITNESS: Right, exactly.

21 THE COURT: Having reviewed that report, without  
22 reading from it or reading it into the record, does it refresh  
23 your recollection about whether you did a GRASE study on this  
24 substance?

25 THE WITNESS: Yes, it does.

M1PPFIS6

Bowman - Direct

1 THE COURT: Thank you.

2 THE WITNESS: And I did.

3 BY MS. MORTAZAVI:

4 Q. All right. And if you could make sure to put away the  
5 report if you haven't already, Dr. Bowman?

6 THE COURT: Just flip it over.

7 A. That should work just fine.

8 Q. Now, having been refreshed on your analysis, do you recall  
9 what your conclusions were after conducting your GRASE analysis  
10 for BPB?

11 A. Yes. BPB is an unapproved new animal drug, and I did not  
12 find any well-controlled studies, adequate well-controlled  
13 studies to support its use in horses.

14 Q. Thank you, Dr. Bowman. Turning back to this label, are you  
15 familiar with the terms, which does not appear here, but the  
16 term "DOM"?

17 A. In reference to?

18 Q. In reference to label information. And I'll have  
19 Ms. Jung --

20 A. Oh, date of manufacturer, yes.

21 Q. All right. And here on this label, I'll correct myself,  
22 DOM does appear on this label of BPB.

23 There are the words "EXP." Are you familiar with  
24 that?

25 A. Yes, that's the expiration date.

M1PPFIS6

Bowman - Direct

1 Q. And what's the date of manufacturer and the expiration date  
2 listed here?

3 A. Date of manufacture is November of 2016; expiration date is  
4 November of 2019.

5 Q. Thank you.

6 If you could take down these exhibits, Ms. Jung.

7 I'm going to direct the jurors to once again retrieve  
8 their transcription binders, and please turn to tab 120-AT.  
9 I'll have Ms. Jung pull up that same exhibit and prepare  
10 Government Exhibit 120-A.

11 THE COURT: Everyone okay? All right.

12 Ms. Mortazavi.

13 MS. MORTAZAVI: Ms. Jung, if you could please play  
14 Government Exhibit 120-A.

15 (Audio played)

16 Thank you, Ms. Jung.

17 And for the record, that was a call dated March 7,  
18 2019, between Seth Fishman and Mary Fox, as indicated on  
19 Government Exhibit 120-AT.

20 BY MS. MORTAZAVI:

21 Q. Dr. Bowman, you spoke about FDA CVM's oversight of  
22 manufacturer after a drug has been approved; do you recall that  
23 testimony?

24 A. Yes.

25 Q. Once a label is approved for a new animal drug, under what

M1PPFIS6

Bowman - Direct

1 circumstances can the manufacturer make changes to the label?

2 A. The manufacturer can make changes to the label by  
3 submitting a supplemental application. If all it is making  
4 a change to the label, for example, if they want to add more  
5 detail to the label, explaining how the drug is used or what it  
6 could be good for, that might not require additional data.

7 However, if they wanted to change the ingredients and,  
8 therefore, have to change the label, or if they wanted to add  
9 an indication, then data would be required. It would be a  
10 supplement with data.

11 Q. All right.

12 MS. MORTAZAVI: Your Honor, I'd like to read yet  
13 another stipulation into the the record. It is Government  
14 Exhibit 9005.

15 If called as a witness at trial, a record custodian  
16 for Microsoft Corporation, Microsoft, and for each of  
17 Government Exhibits 3401 through 3410, and 3412 through 3457,  
18 would testify that Government Exhibits 3401 through 3410, and  
19 3412 through 3457, are true and correct copies of electronic  
20 records, including e-mails and their attachments, associated  
21 with the e-mail account SethFishman@Hotmail.com, made and  
22 maintained by Microsoft.

23 And if the Court is comfortable with this, I'd like to  
24 move on to the second paragraph without reading the additional  
25 matter.

M1PPFIS6

Bowman - Direct

1 THE COURT: That's fine.

2 MS. MORTAZAVI: All right. In paragraph 2 of this  
3 exhibit: If called as a witness at trial, a record custodian  
4 for 1&1 IONOS, I-O-N-O-S, and for each of Government Exhibits  
5 3301 through 3314, 3316 through 3326, 3399-A, 3399-B and  
6 3399-C, would testify that those government exhibits are true  
7 and correct copies of electronic records, including e-mails and  
8 their attachments, associated with the e-mail account  
9 Seth@Equestology.com made and maintained by 1&1 IONOS.

10 And again, your Honor, I will skip the portions that  
11 follow and read paragraph 3.

12 If called as a witness at trial, a record custodian  
13 for Google LLC, Google, and for Government Exhibit 1600 would  
14 testify that Government Exhibit 1600 is true and correct copy  
15 of an electronic record associated with the e-mail account  
16 JNavarroStables@Gmail.com, made and maintained by Google.

17 And I'll skip to the final portion of this  
18 stipulation, which states: It is further stipulated and agreed  
19 by and between the parties that the aforementioned government  
20 exhibits and this stipulation, which is Government  
21 Exhibit 9005, may be received in evidence at trial.

22 And the government offers the stipulation, Government  
23 Exhibit 9005, and all the exhibits referenced therein into  
24 evidence.

25 THE COURT: All right. The stipulation itself, 9005,

M1PPFIS6

Bowman - Direct

1 and all of the exhibits, the numbers of which Ms. Mortazavi  
2 have read into the record, are admitted in evidence in this  
3 case.

4 (Government's Exhibits 9005, 3401-3410, 3412-3457,  
5 3301-3314, 3316-3326, 3399-A, B, and C, 1600 received in  
6 evidence)

7 MS. MORTAZAVI: Thank you, your Honor.

8 Ms. Jung, could you please pull up Government  
9 Exhibit 3323.

10 BY MS. MORTAZAVI:

11 Q. And I'd like to review that with you, Dr. Bowman.

12 Thank you, Ms. Jung.

13 Could you read the header information on the e-mail  
14 that is depicted in Government Exhibit 3323?

15 A. It's from John Pundyk to Seth Fishman, Lindsay Whitaker and  
16 Geoff Vernon.

17 Q. And what is the subject of this e-mail?

18 A. The subject: Equitosan, ACTH and TB-7 labels, dated Friday  
19 April 28th, 2017.

20 Q. And could you please read the body of the e-mail, starting  
21 with "As per our conference call yesterday"?

22 A. "As per our conference call yesterday, here are  
23 alterations/additions I need made to the Equitosan" -- I can't  
24 say anything -- "label. Change 50ml to 20ml, change the  
25 verbiage to dose and route of administration as recommended by

M1PPFIS6

Bowman - Direct

1 a licensed veterinarian. All products must have visual  
2 association and familiarity in design and appearance. Once  
3 this has been done, please send Dr. Vernon and myself for final  
4 approval."

5 Q. All right. And below, a few lines below the portion that  
6 you just read is the term "ACTH" and the lines, "As you heard  
7 yesterday, Dr. Vernon aquates the color red to danger. So  
8 let's go with the older label with the horse head in gunmetal  
9 and the softer colored label (blue)."

10 There appears to be a numbered list under that. Could  
11 you please read that numbered list into the record?

12 A. "One. Add the verbiage 'RnD peptide'; also, add 'dose and  
13 route of administration as recommended by a licensed  
14 veterinarian;' and three, all products must have visual  
15 association and familiarity in design and appearance."

16 Q. And under TB-7, which appears under the portion that you  
17 read, can you read the numbered list under TB-7, please?

18 A. "No. 1, add the verbiage 'RnD peptide;' No. 2, also add  
19 'dose and route of administration as recommended by a licensed  
20 veterinarian;' and three, all products must have visual  
21 association and familiarity in design and appearance."

22 Q. Are you familiar with the term RnD, Dr. Bowman?

23 A. In my typical experience it means research and development.

24 Q. And you testified about research and development, correct?

25 A. Correct.

M1PPFIS6

Bowman - Direct

1 Q. And you previously testified that drugs that are intended  
2 for research and development are proposed to the FDA as part of  
3 the new animal approval process; is that correct?

4 A. That is correct.

5 Q. All right.

6 Ms. Jung, if you could please take down this exhibit.

7 Dr. Bowman, in what ways does the FDA regulate  
8 promotional materials for a drug?

9 A. Promotional materials for approved drugs are submitted  
10 annually as part of the annual report for review and  
11 consistency with the application, to ensure that companies  
12 aren't either intentionally or accidentally including new  
13 indications or new doses in their promotional materials.

14 As far as unapproved drugs, we use all of that  
15 information as evidence of intended use and tend to use that as  
16 evidence if we take any regulatory actions.

17 Q. And, Dr. Bowman, you spoke about changes to labeling and  
18 the route through which a manufacturer would have to get label  
19 changes approved. Do there have to be processes followed for  
20 changes when promotional material is altered?

21 A. No, I don't -- there is no pre-approval requirement for all  
22 promotional material. So a company can change their  
23 promotional materials and start using them, but then when they  
24 submit them with their annual report, if they have changed them  
25 in such a way that they're no longer consistent with the

M1PPFIS6

Bowman - Direct

1 approval, they are likely to receive a letter from us.

2 Q. What type of letter?

3 A. It could be an advisory letter or a warning letter.

4 Q. And why would they receive that letter if their promotional  
5 material is no longer consistent with the drug that they are  
6 distributing?

7 A. Because then they are not staying consistent with their  
8 approved application.

9 Q. All right.

10 Ms. Jung, could you please pull up Government  
11 Exhibit 319-K, which is a record of Equestology, Inc. that's in  
12 evidence.

13 Dr. Bowman, I'd like to review this with you. If you  
14 look at the very top of this exhibit, it appears to be an  
15 e-mail from Lisa Ranger to Seth Fishman dated May 4th, 2016.  
16 Could you please read the subject line?

17 A. "Need description and recommendation."

18 Q. And looking at the bottom of this thread, can you -- at the  
19 e-mail that appears to be dated May 4th, 2016, at 2:28 p.m.  
20 from Lisa Ranger. Can you read the body of that e-mail?

21 A. "On your Heptam product please. In writing. So I can  
22 print."

23 Q. And looking one line up, what appears to be the response to  
24 that e-mail?

25 A. "What do you mean."

M1PPFIS6

Bowman - Direct

1 Q. And is that sent from Seth Fishman on May 4th, 2016?

2 A. Yes, it is.

3 Q. And above that, what's the response from Lisa Ranger?

4 A. "I need a description of the product."

5 Q. Ms. Jung, if you could take that down, and please pull up  
6 Government Exhibit 319-M.

7 And again, Dr. Bowman, this appears to be an e-mail  
8 chain. At the top is an e-mail from Lisa Ranger to Mary Fox  
9 and Seth Fishman. It's dated May 24th, 2016, with the subject  
10 Re: NPX. Looking at the very bottom of this chain, can you  
11 please read the date, time and sender for the e-mail, and then  
12 the body of the e-mail itself?

13 A. The bottom of the chain by date or by position?

14 Q. The bottom of the chain by date. It's May 23rd, 2016, at  
15 3:32 p.m. from Mary Fox.

16 A. Okay.

17 Q. If you could read the lines that follow, please?

18 A. "Seth needs to know how many NPX you want for the year, if  
19 possible, so he can plan production for the lab."

20 Q. And looking at the top e-mail, could you read the body of  
21 that message dated May 24th, 2016, starting with "At this  
22 point, 50"?

23 A. "At this point, 50. It would sell more, but people need to  
24 know it exists. If he could write a short description of each  
25 of the new products below in understandable layman's terms, it

M1PPFIS6

Bowman - Direct

1 would help his sales tremendously."

2 Q. And below there appears to be a list of products. Do you  
3 see the name "EPM Double Kill"?

4 A. Yes.

5 Q. Could you read the lines that follow?

6 A. "It's a great seller but a description could make it get  
7 there more and have even greater sales."

8 Q. And then the line, in all caps, that follows after that,  
9 please?

10 A. 'any other new product he has that he wants to send me."

11 Q. Thank you.

12 Ms. Jung, you can take that exhibit down. If you  
13 could please pull up Government Exhibit 319-U, and if you could  
14 zoom in, Ms. Jung, on the portion of the e-mail that's dated  
15 Wednesday, January 4th, 2017, at 9:26 a.m. And, Ms. Jung, to  
16 make it easier to read, you can just focus solely on the header  
17 information and the few lines that follow, not the entirety of  
18 the message. Thank you very much.

19 Dr. Bowman, do you see that this is an e-mail from  
20 Mary Fox to Seth Fishman dated January 4th, 2017?

21 A. Yes.

22 Q. Could you read the subject line of this e-mail?

23 A. "Lisa needs descriptions to sell more of this product for  
24 you and any other new items you are considering."

25 Q. And could you please read the body of the e-mail as it

M1PPFIS6

Bowman - Direct

1 appears here?

2 A. "I also need a short explanation, in horseman's terms,  
3 about his new products. If he wants to open the door to them,  
4 he needs them to be able to ask and understand the product."

5 Q. Thank you, Ms. Jung.

6 Could you please turn to Government Exhibit 319-J, and  
7 again, this is a record of Equestology, Inc. And if you could  
8 focus, Ms. Jung, on the lower e-mail that's dated Wednesday,  
9 January 2nd, 2019, at 1:32 p.m.

10 And for the record, that appears to be an e-mail from  
11 Lisa Ranger to Seth Fishman that's dated January 3rd, 2019 --  
12 pardon me, January 2nd, 2019.

13 Could you read the subject line of this e-mail,  
14 Dr. Bowman?

15 A. "Item description needed."

16 Q. And could you read the body of this e-mail?

17 A. "Can you please send a short description of each item,  
18 please."

19 Q. And what appears below that?

20 A. "No. 1, B3, this is a blood builder that is used five to  
21 six days prior. Usually it takes two weeks to see results.  
22 The dosing is once every two weeks. I would really stay low  
23 key on this one.

24 "No. 2, BPR Blue, strong analgesic. Like other  
25 products, I would start with one-half cc IV and work my way up.

M1PPFIS6

Bowman - Direct

1 "No. 3, ITTP Plus. ITTP plus other ingredients. ITTP  
2 increases oxygen release. Compared to what's sold online, it's  
3 less than half the price. Most people are using one-half  
4 bottle night before and remainder of bottle four to five hours  
5 before event.

6 "4, VO2 Max. HP Bleeder Plus with additional  
7 ingredients. Usually 10 mls, four to five for prior to race.

8 "5, P3 Pentosan Platinum Plus. Equivalent to dose of  
9 pentosan and one bottle of Polyglycan."

10 Q. And, Dr. Bowman, if you could continue reading the  
11 sentences that follow?

12 A. "I have other products and will start organizing them. I  
13 have stuff you can use the day before that is far better than  
14 bute and banamine on many levels."

15 Q. Thank you.

16 And, Ms. Jung, if you could take down this exhibit,  
17 and pull up Government Exhibit 319-N, which is yet again a  
18 record of Equestology, Inc. and if you could focus on the text,  
19 please.

20 Dr. Bowman, do you see at the top of this e-mail that  
21 this is a message sent from Lisa Ranger to Seth Fishman on  
22 July 2nd, 2019?

23 A. Yes.

24 Q. And below that, do you see a lower-in-chain e-mail sent  
25 from Seth Fishman dated July 2nd, 2019?

M1PPFIS6

Bowman - Direct

1 A. Yes.

2 Q. What's the subject line of this e-mail chain?

3 A. Panacin.

4 Q. All right. And could you read the body of the e-mail  
5 following the header information on two July 2nd, 2019?

6 A. Which one do you want to do first --

7 Q. Sure.

8 A. -- 3:15 or 3:48?

9 Q. At -- oh, pardon me. Thank you for the correction. The  
10 e-mail at 3:48 p.m.

11 A. Okay.

12 Q. I believe they may have been sent around the same time.  
13 The line starting "According to a study at Dubai Equine"?

14 A. "According to a study at Dubai Equine, 10 cc's, 24 hours,  
15 and 10 cc four hours before stress was equivalent to one dose  
16 of Banamine. Use IV because IM injections can be painful."

17 Q. And looking below that, at the e-mail that preceded the  
18 e-mail that you just read out, could you please read the body  
19 of that e-mail?

20 A. "Correct way to use, different options on use if there are  
21 any, so I can forward to clients."

22 Q. Thank you.

23 Ms. Jung, you can take down this exhibit, and could  
24 you please pull up Government Exhibit 319-O, which is again a  
25 record of Equestology, Inc.

M1PTFIS7

Bowman - Direct

1 BY MS. MORTAZAVI:

2 Q. Dr. Bowman, do you see this is an email from Lisa Ranger to  
3 Seth Fishman dated February 23, 2018?

4 A. Yes.

5 Q. And there appears to be an attachment to this email. Could  
6 you read the name of the file that's attached?

7 A. The attachment is inventory - doc summary.PDF.

8 Q. What the body of that top email?

9 A. Here you go.

10 Q. There appears to be a lower chain email dated  
11 February 23rd, 2018 sent from Seth Fishman. Could you please  
12 read the text of that lower-in-chain email?

13 A. When you have a chance, please send me the current prices  
14 we are charging for the stuff I make.

15 MS. MORTAZAVI: Ms. Jung, if we could take down this  
16 exhibit and please pull up Government Exhibit 709. And this is  
17 an item that was retrieved from a computer that was found at  
18 Lisa Giannelli's residence.

19 Q. Starting with page 1, Dr. Bowman, looking at the categories  
20 that appear in bold, looking at the first category, adrenals  
21 thyroid glands, do you recognize on this list any FDA approved  
22 drug names?

23 A. Well, as we discussed, I mean ACTH is an FDA-approved drug,  
24 I just don't know if any of these are the ones that are  
25 approved.

M1PTFIS7

Bowman - Direct

1 Q. Are there any names appearing here that appear to be APIs  
2 or active pharmaceutical ingredients?

3 A. Yes.

4 Q. Can you name one or two examples?

5 A. Well, ACTH powder is an active pharmaceutical ingredient,  
6 and there is also the -- it's hard to tell because you don't  
7 know what dosage form they're in, if they're in finished dosage  
8 forms or not. Some of the powders may be for administration.  
9 The thyroid powder is an unapproved drug, however it is  
10 marketed. Thyro-L is a marketed the version of that drug.  
11 That's the drug listed with the FDA.

12 Q. Thank you, Dr. Bowman. We can go back to the original  
13 exhibit, 709.

14 Looking at that second category, Dr. Bowman  
15 antiinflammatory relax pain, does that category make a  
16 representation about the intended uses for the drugs that  
17 appear here?

18 A. Yes.

19 Q. Can you explain?

20 A. Well, by categorizing them all as antiinflammatory,  
21 relaxation or pain, the drugs in this category are intended for  
22 all or one -- at least one of those three uses, so they're  
23 either pain relievers, muscle relaxants or they're  
24 antiinflammatory by nature.

25 Q. Dr. Bowman, looking at the bottom of the first column the

M1PTFIS7

Bowman - Direct

1 product that is three up from the very last one, Flunixin, you  
2 testified about Flunixin previously, is that right?

3 A. Yes.

4 Q. Is that a product that requires a prescription?

5 A. Yes, it is.

6 Q. Looking at the product one up from that, which is Banamine,  
7 are you familiar with Banamine?

8 A. Yes.

9 Q. Does that require a prescription?

10 A. Yes.

11 Q. Are there any other items appearing in this categorical  
12 list that appear to be drugs that would require a prescription?

13 A. Yes.

14 Q. Could you give us one or two examples?

15 A. Well, there is Acepromazine pills, Bute powder, Bute  
16 tablets, Bute Phenylbutazone is probably an injection,  
17 Dexamethazone, Flunixamine, gentamicin, which brand name is  
18 Gentacin, Isoxoprine. Those are all prescription drugs. Most  
19 of the drugs in this category are prescription drugs.

20 Q. Thank you, Dr. Bowman.

21 MS. MORTAZAVI: And Ms. Jung, you can take down this  
22 exhibit.

23 I will ask the jurors to pick up their transcription  
24 binders and turn to tab 122CT, and I will ask Ms. Jung to  
25 please pull up Government Exhibit 122CT and prepare Government

M1PTFIS7

Bowman - Direct

1 Exhibit 122C.

2 And for the record, this is a portion of a call  
3 intercepted on March 31, 2019 between Seth Fishman and an  
4 unidentified female.

5 If any jurors still need it, it's tab 122CT. 122CT.

6 Ms. Jung, please play Exhibit 122CT.

7 (Audio recording played)

8 MS. MORTAZAVI: Ms. Jung, if you could take down those  
9 exhibits and the jurors could put away their binders.

10 And while they're doing so, I will have Ms. Jung  
11 please pull up Government Exhibit 3404. That exhibit is in  
12 evidence subject to the prior stipulation. It is an email from  
13 the email address sethfishman@hotmail.com.

14 And Ms. Jung, if you could actually go to the last  
15 page in this email.

16 Q. Dr. Bowman, do you see that this is an email from Seth  
17 Fishman, sethfishman@hotmail.com, to an individual named  
18 Karthik Ragavan (ph)?

19 A. Yes.

20 Q. What is the date on this email?

21 A. May 8, 2017.

22 Q. Could you please read the body of the email?

23 A. It's been a long time. Hope you are doing well. I have a  
24 group of investors that would like to invest in registering  
25 Pentosan for veterinarian use in USA. I have one of company in

M1PTFIS7

Bowman - Direct

1 India that is very interested in the deal. As we have a long  
2 history and you are USA-based, I would offer you the first  
3 right of refusal. Please let me know if you are interested in  
4 this deal.

5 Q. Dr. Bowman, are you familiar with Pentosan?

6 A. Yes.

7 Q. What is it?

8 A. It's a drug that is commonly used in horses to inject  
9 joints to treat osteoarthritis, synovitis, also approved in  
10 people to treat idiopathic cystitis, I believe.

11 Q. Is it FDA approved in the United States for animal use?

12 A. No, not for animal use, only human use.

13 MS. MORTAZAVI: Ms. Jung, please take down this  
14 portion of the exhibit and go back to the original exhibit,  
15 3404. I'm sorry, if you could go two pages over, please.

16 Q. At the very bottom, Dr. Bowman, do you see the email  
17 response from Karthik Ragavan to Seth Fishman?

18 A. Yes.

19 MS. MORTAZAVI: May 8, 2017 at 11:04 p.m.

20 Ms. Jung, if we could actually go back to the original  
21 page, it's the portion at the very bottom, 11:04 p.m., and if  
22 you could turn to the next page, Ms. Jung, where it appears  
23 that that message continues.

24 Q. Could you read the body of that email, please, Dr. Bowman.

25 A. Yes. I would like to know more about the deal, what will

M1PTFIS7

Bowman - Direct

1 Sentio's role be, et cetera.

2 MS. MORTAZAVI: Ms. Jung, please go back to page 2 of  
3 this exhibit.

4 Q. And we're going to work up the chain, Dr. Bowman, and read  
5 these portions of this email into the record. Looking at the  
6 May 8, 2017, 10:05 p.m. email from Seth Fishman to Karthik  
7 Ragavan, could you please read the body of the email.

8 A. I will buy API and have you bottle, if interested.

9 Q. An email response from Mr. Ragavan on Monday, May 8, 2017  
10 at 11:07 p.m. to Seth Fishman, could you please read the body  
11 of that email appearing in the center of page 2.

12 A. What about regulatory? That is a major project. CMC,  
13 clinical trials, et cetera. You are looking at roughly five  
14 years. It's not just buying API. As a manufacturer, we will  
15 need to submit an entire dossier to CVM. That alone will cost  
16 2 to 3 million.

17 Q. Dr. Bowman, we previously referred to FDA CVM, is that also  
18 referred to as simply CVM?

19 A. Yes, it is.

20 Q. Is that a reference to your place of employment?

21 A. Yes.

22 Q. And by that, I mean CVM appearing in this email in  
23 Government Exhibit 3404.

24 A. Yes, I believe so.

25 Q. And looking at the email response above that dated Monday,

M1PTFIS7

Bowman - Direct

1 May 8, 2017, at 10:23 p.m. from Seth Fishman to Mr. Ragavan,  
2 could you please read the body of that email.

3 A. I told the investors in the group that it would cost  
4 serious money. They're well aware of the costs. An Indian  
5 group was interested and willing to share in expenses. They  
6 are looking, I think, more about for human. I'm not sure if  
7 they genuine in their offer and requirements for human maybe  
8 exponentially more. If you have an interest, I will discuss  
9 with you. Indian group selling worldwide and mostly human. I  
10 need to know if you're interested. I also still wanting to  
11 know if you are interested in formulating and bottling, as we  
12 discussed, for a medical device to start.

13 MS. MORTAZAVI: And Ms. Jung, if you could turn to  
14 page 1 of this email chain.

15 Q. Dr. Bowman, do you see here the response to the email you  
16 just read out dated May 8, 2017 at 11:28 p.m. from Mr. Ragavan  
17 to Seth Fishman?

18 A. Yes.

19 Q. Could you read the body of that email.

20 A. I am very familiar with the Indian company. I am not  
21 interested in medical device. We are now an FDA-approved site  
22 and we will get in serious trouble if we are making drugs and  
23 selling them at device. We just got DIROBAN registered, by the  
24 way. We have to know a lot more before we can say more.  
25 Without a plan in front of us, it will be difficult to commit

M1PTFIS7

1 to it. If you have any high-level plan, that would be good to  
2 review.

3 Q. Looking at the final email in this chain at the very top of  
4 page 1, that's an email from Seth Fishman to Mr. Ragavan dated  
5 May 12, 2017 at 12:37 a.m. Could you please read the body of  
6 this email after Karthik.

7 A. I have several high-level hunter jumper vets using the  
8 Pentosan that I made. They're very happy and they're  
9 interested in making it 100 percent legitimate. I know they  
10 have the money behind them if they want to pursue the idea. If  
11 you feel your company is up to the task, please give me an  
12 approximate cost to proceed. In the interim, do you have  
13 Pentosan to sell? I purchased from the other group and the  
14 product was good. If you are now an FDA-approved site and  
15 already in the USA, it would obviously be better to work with  
16 your group.

17 MS. MORTAZAVI: Thank you, Dr. Bowman.

18 Ms. Jung, you can take down this exhibit.

19 And your Honor, no further questions.

20 THE COURT: Thank you very much.

21 All right. Ladies and gentlemen, we're going to  
22 conclude for the day then, and when we pick up tomorrow we'll  
23 have cross-examination by Dr. Fishman's counsel.

24 So thank you all very much. I hope you all have a  
25 good evening.

M1PTFIS7

1 Dr. Bowman, you remain under oath, and we'll recall  
2 you first thing tomorrow morning.

3 THE WITNESS: Thank you.

4 THE COURT: All right. We'll adjourn for the day  
5 then. Thank you all very much for your attention today.  
6 Please be back tomorrow morning at about 9:15 so we can start  
7 about 9:30. Thank you.

8 (Jury not present)

9 THE COURT: Dr. Bowman, you're excused for the  
10 evening.

11 Is there anything we need to discuss, Mr. Adams?

12 MR. ADAMS: As soon as Dr. Bowman is out of the room  
13 I'm happy to run through the batting order.

14 THE COURT: Thank you.

15 MR. ADAMS: Otherwise, nothing else from us.

16 (Pause)

17 THE COURT: All right. Mr. Adams?

18 MR. ADAMS: Thank you, your Honor. So I expect that  
19 after cross-examination of Dr. Bowman and any redirect in the  
20 morning we'll move to Dr. Cole, who I expect we'll finish the  
21 direct and be into cross, assuming what cross-examination may  
22 look like, and we may well begin with Ross Cohen in the  
23 afternoon tomorrow. And there's some possibility, depending on  
24 length of cross-examination, that we would even start with  
25 Special Agent Aaron Otterson.

M1PTFIS7

1 THE COURT: I'm sorry, I'm having trouble hearing you.

2 MR. ADAMS: Special Agent Aaron Otterson, who will  
3 walk through one of the searches. I believe that we are on  
4 track -- again, with some assumptions about what  
5 cross-examination might look like, I believe the government is  
6 on track potentially to rest its case on Friday.

7 THE COURT: Okay. All right. Anything from you all,  
8 Mr. Sercarz?

9 MR. SERCARZ: Yes, your Honor. Your Honor, we have  
10 had periodic discussion about the parameters for expert witness  
11 testimony. I'm thinking ahead to the direct examination of  
12 Dr. Cole, and I would point out that with this witness, and  
13 this is just to orient you, my concerns on this subject of  
14 opinion evidence regarding the safety and efficacy of my  
15 client's products beyond the statement that a drug is deemed  
16 unsafe pursuant to the FDA.

17 THE COURT: And you're talking about Dr. Cole now.

18 MR. SERCARZ: Yes. The government has with this  
19 witness -- and I did not object to it -- used the formulation  
20 that there have been GRASE studies. I'm not sure what that  
21 last letter is for. I understand GRAS is Generally Regarded As  
22 Safe. And that they have not found any studies to indicate  
23 that Dr. Fishman's drugs are safe. I would urge that upon the  
24 Court and suggest that if Dr. Cole is going to come in and  
25 start offering opinion testimony regarding the safety and

M1PTFIS7

1 efficacy of Dr. Fishman's products, it is, A, duplicative, and  
2 B, anything further than reference to the general scientific  
3 consensus, which is necessary for FDA approval, would be highly  
4 prejudicial and would carry no marginal additional probative  
5 weight. You may recall that I pulled for the Court Dr. Cole's  
6 article regarding Equestology products. I'm not certain where  
7 she's going.

8 THE COURT: I'm not either.

9 MR. SERCARZ: I'm not certain how it differs. But I  
10 wanted the Court to see where we are at this stage in order to  
11 consider how much further is necessary on the subject of safety  
12 and efficacy of Dr. Fishman's products, because I'm going to  
13 object to anything further.

14 Indeed, in the wake of the breadth and scope of this  
15 testimony, I would renew my objection to preclude any testimony  
16 by an additional witness going to the issue of the safety and  
17 efficacy of Dr. Fishman's products. If the Court does not find  
18 that that is necessary, I would urge upon the Court that the  
19 government should be allowed to do no more than refer to these  
20 types of studies regarding products other than those that were  
21 covered in Dr. Bowman's testimony.

22 THE COURT: Anyone want to be heard from the  
23 government?

24 MR. ADAMS: Dr. Cole will be my witness, your Honor.  
25 I think that Mr. Sercarz may be laboring under some

M1PTFIS7

1 misimpression about what Dr. Cole's testimony is really about.

2 What I expect to elicit from Dr. Cole is largely  
3 expert testimony about the effect of the various substances  
4 offered by Equestology, and specifically the effect in the body  
5 of a racehorse and a racing animal, and even more specifically,  
6 any performance-enhancing effect of those drugs, because it  
7 goes to the fact that the substances themselves are drugs, that  
8 they have an effect, and the intent of Dr. Fishman is squarely  
9 at issue in this case.

10 THE COURT: How does it go to the intent to defraud or  
11 mislead?

12 MR. ADAMS: Insofar as the drugs are performance-  
13 enhancing drugs and non-testable performance-enhancing drugs,  
14 it goes directly to his intent not to, in his words, provide  
15 for the health and safety of the animals but rather to provide  
16 for a secret non-testable agent to allow people to sneak past  
17 anti-doping regulators.

18 THE COURT: I think we'll have to see where the  
19 questioning goes. On a high plane level, academically it  
20 sounds like it might be okay, but as I say, I will have to hear  
21 your questions and your objections and I will rule on them  
22 accordingly, but I will not preclude her from testifying.

23 Anything else?

24 MR. ADAMS: Not from here, your Honor.

25 THE COURT: Everybody have a good evening and I'll see

M1PTFIS7

you here about 9:15 tomorrow morning ready to go at 9:30.

If there's anything further, you need to let us know by this evening so that we can all meet a little earlier if need be. I don't want to delay starting with the jury. Okay?

MR. ADAMS: Thank you, Judge.

THE COURT: Thank you everyone. Have a good night.

(Adjourned to January 26, 2022 at 9:15 a.m.)

# INDEX OF EXAMINATION

Examination of:	Page
DANIEL FOLENSBEE	
Direct By Ms. Mortazavi . . . . .	371
JEAN BOWMAN	
Direct By Ms. Mortazavi . . . . .	386

## GOVERNMENT EXHIBITS

Exhibit No.	Received
9011, 101-A through 115-C, 117-A . . . . .	382
through 143-D, 160-A through	
173-A, 190-A through 192-A,	
and 199-A through 199-B	
9002 . . . . .	431
700 to 715 . . . . .	432
1000 to 1003, 1005 to 1011, and 1013 to . . .	437
1053	
9012, 1400 through 1420, 9500 through . . . .	442
9505, 1500 through 1511, 9600	
through 9604, 1200 through	
1222, 9200 through 9216, 1100	
through 1128, and 9300 through	
9311	
9006, 300 through 320E and 320FA through 331	454
9015, 9020-9086, 6000-6005, 1300-1317, . . .	505
5000-5018, 9100-9122,	
1800-1806, 9400-9414	
9005, 3401-3410, 3412-3457, 3301-3314, . . .	514
3316-3326, 3399-A, B, and C,	
1600	